The Microbiological and Mechanical Integrity of Batch Tested and Individually Tested Surgical Gloves

MASTER OF MEDICAL SCIENCE THESIS

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Abstract

The most common surgical gloves used at the Royal Hobart Hospital are 'Individually Tested' (IT) gloves, in which each glove is tested for leaks by the manufacturer prior to sterilization and packaging. A cheaper brand of glove is available in which sample gloves from manufactured batches are tested for leaks (BT), but not each glove. The latter gloves were widely rejected by surgeons on the theoretical ground that there would be more perforations, and consequently more wound infection and greater exposure of staff to patient pathogens. However no objective study had been done to test this conjecture.

The aims of this study were to compare the integrity of the two brands of gloves by mechanical and microbiological methods, and to compare the incidence of post-operative wound infection following the use of either brand.

110 unused gloves of each brand were tested for leaks. 318 IT and 278 BT gloves were then tested after clean surgery, for mechanical leaks. Scrub-team member's gloves and hands were cultured post-surgery. Wound infection rates were compared.

The pre-use perforation rate was not significantly different. The macroperforation rate for IT gloves was slightly but statistically significantly higher than for BT gloves, and no bias in types of operations or in staff members could be uncovered to account for this.

Growth of normal skin flora was found on virtually every wearer's hands after removal of gloves, suggesting a failure of current scrub techniques or solutions to eliminate skin flora. Furthermore these bacteria were commonly cultured from the outside of the gloves at the conclusion of surgery, indicating development of microporosity of the glove-latex during surgery. There was a statistically significant difference in the glove outer-surface bacterial detection rates between the brands (BT>IT) indicating a difference in latex properties between brands. It is suggested that a standardized form of this test could be developed as a quality measure of surgical gloves.

A final finding was the absence of translation of macroperforation rates or bacterial culture rates into morbidity as measured by wound infection. It could be concluded that for this type of surgery, the detected glove differences are irrelevant with regard to patient morbidity. However caution is suggested in extending these findings to situations of known patient infectivity (eg. HIV or viral hepatitis) or to cases where any contamination could be a serious problem (eg. joint surgery or neurosurgery). The data adds weight to the strategy of double gloving.

STATEMENT

This thesis contains no other material which has been accepted for the award of any other degree or diploma in any tertiary institution and that, to the best of my knowledge and belief, this thesis contains no material person except where due reference is made in the text of the thesis.

ACKNOWLEDGMENTS

This work is dedicated to my supervisor Dr. Stephen Wilkinson who has patiently supported my completion of this study through the difficult circumstances which I faced soon after emigrating to Australia. I hope that this study will provide definitive material for both cost-efficient and evidence-based practice with regard to the use of surgical gloves in the operating theatre.

I would like to acknowledge with gratitude, support from both Profeel and Ansell glove manufacturers.

With gratitude I also acknowledge the help of staff in the University Department of Surgery and the Clinical Photography Department at the University of Tasmania. I also thank and acknowledge the surgeons and nurses who were willing to add to their already busy and stressful life by adding the extra steps at the end of each operation, which were necessary to participate in this study. This willingness was a clear reflection of the culture of scientific questioning and research which is actively encouraged at the Royal Hobart Hospital both amongst medical and nursing staff, and fostered by the close linkages being developed between the Hospital and University Medical School.

Contents

Aims

1. To compare the integrity of batch tested and individually tested gloves by microbiological and mechanical testing.

2. To compare the incidence of post-operative wound infection following use of either batch tested or individually tested surgical gloves.

1.0 LITERATURE REVIEW

1.1 Background

In 1992 the Royal Hobart Hospital used 123,280 pairs of surgical gloves (Gamex Tm) at an annual cost of $65,338 ($0.53 per pair). This brand of gloves was produced by a process in which every glove was "individually tested" for leakages. The attempted introduction to the hospital of less expensive "batch-tested" surgical gloves (in which sample gloves from each manufacturing batch were tested during the manufacturing process for leakages, rather than the testing of every single glove), was widely opposed by surgeons on the grounds that such gloves would constitute a lowering of standards and would result in higher exposure of staff to patient fluids, an increased exposure of patients to bacteria from the hands of surgical staff, and a consequent increase in wound infection. However no objective study had been carried out to compare these two glove types in relation to wound infection rates, glove perforation rates or degree of bacterial contamination to the surgical team.

When glove perforation occurs bacteria can escape from the hands of the surgical team and contaminate the wound, potentially leading to wound sepsis. Organisms, blood and other body fluids can also pass through perforated gloves from the patient to contaminate the hands of the surgical team. There is good theoretical reason therefore for the surgical team to oppose the introduction of gloves which could offer a significantly less efficient barrier between them and their patients. In the current context of provision of surgical care under great cost constraints however, such opposition must be based on scientific proof of a less efficient barrier, and not merely on supposed theoretical grounds. Nevertheless, there was published evidence that different brands of surgical gloves could be of significantly differing quality with regard to the effectiveness of the barrier provided. For example, the comparative integrity of five different brands of surgical latex glove was tested during minor operations averaging 1h duration was investigated by Sarkilahti (1980). The test method used was determination of the insulation barrier of the latex glove to an electrical current. A total of 370 pairs of gloves were tested during the trial, consisting of 74 sample pairs of each brand. The following results were obtained:

* Brand 1: There were no primarily perforated gloves, and 90% remained intact at the end of the operations.

* Brand 2: 5% were primarily perforated, and 60% remained intact at the end of the operations.

* Brand 3: 4% were primarily perforated, and 53% tolerated the operations undamaged.

* Brand 4: 15% were primarily perforated, and 23% tolerated the operations undamaged.

* Brand 5: 4% were primarily perforated, and 15% tolerated the operations undamaged.

These results indicate that there is a significant difference between the integrity of different brands of surgical latex gloves, and provides support for the surgeon's concern that proper testing of brands of gloves proposed for introduction to a surgical service be carried out.

1.2 Historical Perspective

Rubber gloves have been worn for the dual purpose of protecting the surgical team and protection of wounds from bacterial contamination since the days of Professor Halsted at John Hopkins Hospital. In addition to the mechanical protection offered by gloves, hand-washing in antibacterial soap solutions was introduced to reduce the bacterial count on the skin of the hands of the scrub-team. Over the past fifty years, additional mechanisms and techniques have been applied to reduce contamination of the surgical wound, including wearing of face masks, caps and eye-shields, wearing of full-body suits and helmets with individualised air-flow, laminar air-flow over the operation site, maintenance of slightly above atmospheric pressure in operating theatres with air introduction through vents high in the walls and venting through grates low in the walls, setting of minimum standards for volume of air-flow exchange through theatres, using highly filtered air, reduction of bacterial loads within patients by antiseptic washes, shaves, enemas, and prophylactic antibiotics. Surgical technique has also been modified to minimise direct handling of sharp instruments. Surgical gloves therefore provide only a part, albeit an essential part, of the overall strategy in minimising

cross-contamination between patient and surgical team.

1.3 Glove Perforation Evaluation

Devenish and Miles (1939) examined the patency of 6,965 surgical latex gloves by inflating the gloves with air and testing them under water. Weed and Groves (1942) examined 35,763 gloves for defects by distending them with water and looking for leaks. These two methods subsequently became the common methods of rubber glove testing. Unfortunately, different methods for detection of micro-punctures have been adopted in national standards as in the following examples:

* British Standard for single use, sterilised surgical rubber gloves (BS 4005: 1984): Air inflation test and examination for perforation by visual inspection.

* American standard for rubber gloves (ASTMD.3577): describes an air inflation method with subsequent immersion in water and testing for air bubbles.

In the study of perforation in surgical gloves by Paulssen *et al* (1988), BS 4005:1984 was not recommended for two reasons:

1) holes may be created in parts of the gloves which are not tested by this method;

2) pinholes in the finger tips may not be easily detected by this method.

Penikett and Gorril (1958), and Beck (1959) were the first to report electronic testing of gloves. Two reasons for false positives were noted: firstly, insertion of the gloved hand into the bowl so that the electrolyte solution spilled over the top of the gloves, dampened the gown sleeve, and made contact with the skin, thus triggering the alarm; secondly, moisture on the gown could form a water bridge, allowing current to flow and setting off the alarm. An electronic leak detector similar to that of Penikett and Gorril was developed by Russell *et al* (1966). Hamer (1987) developed an electronic unit for detecting glove leaks in which the surgeon was connected electrically to the patient and did not have to stop surgery in order to check for glove leaks. The electronic glove leak detector had an electronic circuit attached to a sterile electrically conducting bowl filled with a sterile, electrolyte-povidone-iodine solution. An electrically conducting grounding line ran from the circuit and made contact with the bowl. Another line from the electronic circuit made contact with the test subject either via a conducting electrode pasted

on the bare skin of a leg, or to a clip attached on an ear lobe. The gloved hands were dipped into the electrolyte solution one at a time. If a perforation existed in the glove, electrical continuity was established across the leak and energised a buzzer in the electronic circuit. The electronic glove leak detector is shown in Fig. 1.1.

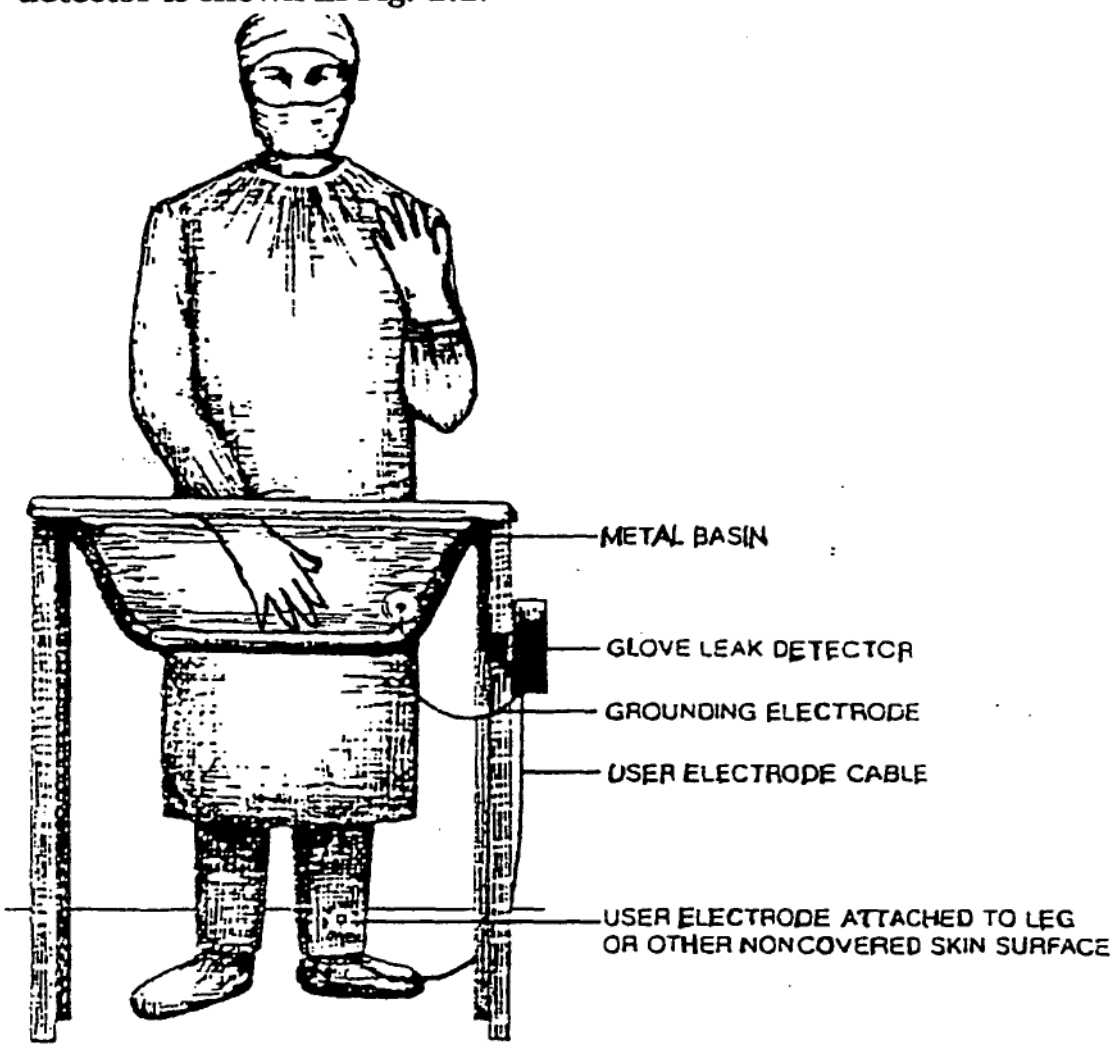


Figure 1.1: The use of an electronic glove leak detector (Hamer 1987).

Electronic point-by-point leak analysis was then used in those gloves that indicated a positive electronic response, yet did not show a water leak with a water pressure test. Electronic point-by-point leak testing is shown in Fig. 1.2.

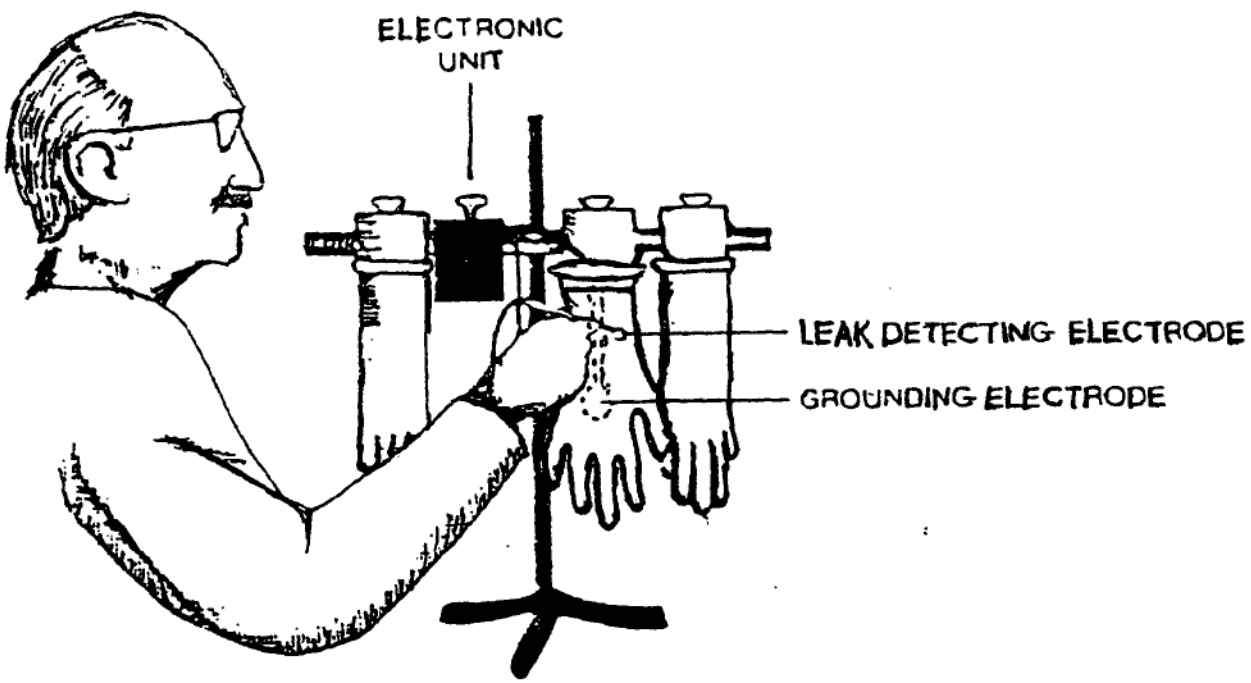


Figure 1.2: Electronic point-by-point leak analysis testing.

In the latter method, the glove to be tested is secured to a special ring stand and carefully filled to the cuff with water. An electronic glove leak detector is used, in which the grounding lead is placed inside the glove with the other lead serving as the localising probe, connected to a pencil-thin holder with a small pellet of water-moistened cotton at the tip. The localising probe is moved slowly over the external surface of the glove, with sound activation indicating electrical conductivity.

Brownron and Gobetti (1990) used a fluorescein dye technique to evaluate glove perforations, with pinholes of a known size placed at controlled distances, and measurement of the area on the fingers or hands covered with dye. In this test the glove is secured vertically with a plastic tube-holder and carefully filled to the cuff with a 1% aqueous fluorescein solution. The glove is then lowered into a large beaker containing distilled water and kept immersed for 3h, after which time aliquots of the water from beaker were tested for fluorescence. Albin *et al* (1992) used a spectrophotofluorimeter (#14-H, Aminco, Salt Lake City, USA) at an excitation frequency of 470nm and emission of 535nm. The fluorescence of the water in the beaker was sampled before and after immersion by the glove, and a percentage of fluorescein emission was calculated.

Study of the risk of viral transmission at operation by electronic monitoring of the surgeon-patient barrier was carried out by Macintyre *et al* (1994). The device (Elper: Selecta UK, Glasgow) monitors up to four members of the surgical team. The surgeon and patient form part of an electrical circuit that is completed when the insulating effect of intact surgical gloves and dry gown is lost. A small pulsatile electrical potential difference (less than 9V peak) produced by a 6x4cm size signal generator connected to each surgeon causes a small direct current (DC) to pass from surgeon to the patient if the barrier is breached. This violation is detected by the electronic system and at a predetermined threshold an alarm sounds. One output terminal of the generator is connected by an adhesive electrode to the surgeon and the other to an overshoe with a conductive strip on its sole. This strip connects through a conductive floor mat to the monitor input. The second terminal of the monitor is linked by an adhesive electrode to the patient. Two types of contact were differentiated on the visual display: a glove hole was indicated by an immediate increase in DC voltage and increased glove porosity by a gradual rise. A total of 113 personnel were monitored using the Elper system during 50 elective general surgical procedures. Of some 266 alarms recorded, 45 were ascribed to glove holes, 86 to wet gowns,

115 to glove porosity and 20 to other causes. The last category included the operator not standing on the conductive mat or touching the base of the operating table, and unmonitored personnel standing on the mat. A total of 45 glove holes occurred in 29 of the 50 operations. The Elper machine appeared acceptably reliable, only two holes identified by subsequent bench testing being missed by the device, because the glove and surgeon's skin were dry. It was recommended that the accuracy of the machine in detecting a breach in the barrier was such that whenever an alarm sounds for whatever reason, gloves and/or gowns should be changed to avoid risk to the surgeon and patient. It was concluded that electronic testing had two major advantages: firstly it was effective throughout the glove; secondly the electronic test was automated and not subject to the alertness of a human examiner.

With the air testing method gloves are inflated on an air-jet. The operator then twists the cuff end of the glove to keep it inflated, and examines the glove visually for holes. Methods have been devised for gloves to be tested on a machine which inflates them and measures any inflation loss, but this suffers from the natural ability of latex to re-seal an unstretched hole. There are two disadvantages of using air testing for holes. One is that the stresses of inflation show that the tested

glove should be discarded and not put into use, which means that air testing can only be used on a statistical sample from production. The second disadvantage is that not all holes are detected by this method. An inflated surgical glove does not equally expand the fingers, but mainly stretches the palm part so that the most important parts (fingers) of the glove can pass an air tested method for hole detection.

1.4 The Incidence and Significance of Surgical Glove Perforation in Single-Glove Studies

Whilst the importance of surgical gloves in providing a barrier between surgical team and patient has been recognised for many years, the incidence of wound infection and risk of transmission of major disease vectors between patients and the surgical team had not been formally studied until relatively recently. The importance of glove punctures was highlighted in 1980, when transmission of Hepatitis B from surgeon to patient (and *vice versa*) was reported. In the collaborative study in 1973 by Cruse and Ford, eight patients undergoing major gynaecologic surgery by a HB Antigen positive surgeon became HB antigen positive. With the

severity of the HIV epidemic now becoming increasingly clear there has been additional interest in the efficiency of the glove barrier. In a study of surgical glove puncture by Church & Sanderson (1980), surgical gloves were tested for punctures by filling them with a dye and squeezing each finger socket and then the palm of the glove in turn. Fine sprays of dye were clearly visible against the white porcelain of a wash basin. All surgical gloves used in one operating theatre were tested on four successive working days. Of 130 gloves tested, 15 (11.5%) were found to be punctured after surgery. On a second occasion the gloves used by a single surgical team during one day of operations were tested. Four operations were performed. Two of eight gloves used by the principal surgeon were found to be punctured, whilst 18 gloves used by assistant surgeons and medical students were intact. Two of eight gloves worn by scrub nurses were also found to be punctured. These results, although based on very small numbers, demonstrated that a high rate of glove punctures can occur during routine surgery. Two features of this study indicated areas for further research:

(1) Only two wearers were aware that punctures had occurred in their gloves;

(2) The principal surgeon and the scrub nurse seemed to be

particularly in danger of perforating their gloves, and this would follow their more frequent manipulation of surgical needles and instruments.

Several studies have indicated that between 10-40% of surgical gloves develop punctures during surgical procedures (Brough *et al* 1988; Cruse and Ford 1973; Hussain *et al* 1988; Maffulli *et al* 1989). In a study of 200 caesarean sections, Smith and Grant (1988), found evidence of glove perforation in 54% of cases, which is the highest frequency of perforation of any surgical operation reported.

Glove perforation in ophthalmic surgery was studied by Prendiville *et al* (1992). After 125 procedures, gloves were collected for the study (303 from the surgeons, 202 from the assistants, 326 from scrub nurses, and 293 from the circulating nurses), and were tested for perforation. All gloves were examined initially for gross tears, (of which there were ten), and these were excluded from the analysis. After initial inspection, all gloves were tested for perforation by filling with a standard volume (500 ml) of water and firmly squeezing. At least one glove was perforated by a member of the surgical team during 64 of the 125 procedures, for an overall perforation rate of 51%. When analysed according to perforations per team member, however, the rates of

perforation differed significantly (surgeons: 0.8%, one of 125 procedures; assistants: 10%, nine of 91 procedures; scrub nurses: 31%, 39 of 125 procedures; and circulating nurses: 22%, 27 of 125 procedures). The differences between assistants, scrub nurses and circulating nurses were significant.

A study of surgical glove perforation during surgery for maxillofacial trauma involving the use of metal plates or wires was carried out by Avery and Johnson (1992). A total of 388 surgical gloves were collected. All patients selected for this study had sustained a traumatic facture of the mandible, and only fractures amenable to treatment by either a wiring-based technique or a small-plate osteosynthesis (SPO) system were selected. The operations were performed by two surgeons and any operating by the assistant surgeon was kept to a minimum. When a glove was known to be perforated it was immediately removed and the reason for perforation recorded. Glove integrity was tested by a water inflation technique. Each glove was fully inflated with water and the cuff twisted tightly closed. Successive fingers were then individually distended with water and squeezed. Operations with one or more glove perforations were compared to operations in which there were no proven glove perforations. This study concluded that the surgical treatment of

mandibular fracture is associated with a relatively high incidence of glove perforation. The overall incidence of perforation when a wiring technique was used was 50.5% with one or more glove perforations, compared to 27.4% in the SPO series. The SPO technique also had a lower total number of perforations per individual glove.

A study by Paulssen *et al* (1988), investigated the frequency of operations in unused gloves using a water-tightness test. Eighty gloves of the same lot of 16 different brands from nine different manufacturers were investigated. Fourteen brands were made of latex rubber and two brands of synthetic rubber. Each glove was filled with 325 ml water, the cuffs twisted through 360° and placed in a rack for 2 min. in order to detect leakage. The highest incidence of gloves with holes was 10% (8 of 80 gloves). However, when another 80 gloves of the same lot were studied, only two gloves with holes were detected. Two of the three brands with the highest number of holes were produced by the same manufacturer. The two brands of gloves made of synthetic rubber were found to be of identical quality to latex gloves with regard to perforations.

Wong *et al* (1993) studied surgical glove punctures during cardiac operations in 48 adult patients undergoing open heart surgery. Gloves worn by surgeons and nurses were collected

and evaluated at the end of each operation. The method of glove testing was air inflation and water submersion, followed by visual inspection for leaks. A total of 514 gloves were collected and tested. One hundred and sixty two gloves had one or more punctures giving an overall puncture rate of 31.5%. There was a total of 221 punctures detected, giving a mean puncture rate of 1.5 per glove. Sixty-one percent of scrub nurses had one or more perforated gloves compared with 23.6% of surgeons. The study showed that glove damage during cardiac operations was not usually detected by the scrub teams.

The effect of suture technique on surgical glove perforation was studied by Chan and Lewis (1989). Sixty cases were randomised to one of two (A & B) methods of wound closure. Closure method (A) restricted handling of the needle to the right hand by using a hand-needle technique. Closure method (B) restricted handling of the needle to the left hand by using an instrument technique. An under-water immersion method was used for detecting glove perforation. There was no significant difference between the two groups in relation to the difficulty of wound closure. Two gloves were found to be damaged when tested before wound closure. The results indicated no difference in the total number of perforations between the two methods, but the great majority of

perforations (84%), both recognised and unrecognised, occurred in the glove that actively handled the needle, the right glove in method A and the left glove in method B.

Modern surgical scrub techniques usually reduce the bacterial counts on surgeons hands the rationale being that when glove perforation occurs, bacteria can escape from the hands and contaminate the wound, leading to wound sepsis. There have been few studies however to assess the magnitude of this risk. In a study of surgical glove perforation by Dodds *et al* (1988) the bacterial contamination of surgeons hands and gloves before and after surgery was measured, and the effect of glove puncture on the bacterial counts noted. The integrity of the gloves was tested by filling them under pressure with tap water. Five hundred and eighty two surgical gloves were tested and 74 perforations were found. Damage was found in 48 of 314 principal surgeon's gloves and in 26 of 268 assistant's gloves. All the surgical teams were right-handed. Of the 48 punctures in the principal surgeon's gloves, 39 were in the left glove, whilst only 16 of the 26 punctures in the assistants gloves were in the left glove. In 85% of cases the perforation was due to a needle prick as opposed to a glove tear. Of 430 unused surgical gloves, 13 were found to contain perforations. In their bacteriological study it was confirmed that hand scrubbing and washing significantly reduced hand

bacterial counts and that glove perforation did not increase the bacterial contamination on the outside of the surgeon's gloves or on the surgeon's hands. A later study by Dodds *et al* (1990) failed to show that breaking the barrier between the surgeon's prepared hands and the patient resulted in any increase in wound sepsis.

Surgical glove perforation in obstetrics was investigated by Christopher *et al* (1991). Seven hundred and fifty four gloves used in surgery and 100 unused control gloves were examined. One hundred and seventeen holes were found in the 754 study gloves, giving a glove perforation rate of 13.3%. None of the 100 unused control gloves exhibited holes ($p < 0.001$). Of the 117 study gloves with holes, only 38 holes were recognised during the surgical procedure. Another 8 holes were detected after degloving when a small spot of blood was found on the wearer's finger. The majority of perforations (54%) went unrecognised by the wearer.

The incidence and circumstances of surgical glove perforation using a sensitive electronic device has been investigated by Green and Compertz (1992). The glove perforation rate during elective general surgery was compared with that seen during an anastomosis workshop. A total of 220 gloves were tested for perforation pre- and post-operatively during elective

general surgical procedures, and during the surgical training workshop 72 gloves were tested. During the surgical procedures, 52 gloves (24%) were perforated. Consultants had a significantly lower perforation rate than trainees, and that for assistants was much lower.

The risk of glove perforation appears to be clearly related to the type and site of surgery (Upton and Bauber 1993; Godin *et al* 1991). The latter study noted an increase in incidence of glove perforation when bone fragments, metal screws, plates, or wires were involved. After Godin *et al* separated the 52 cases involving appliances, bone screws, or wires, the incidence of gross blood contamination to the surgeon's fingers was 23%. The incidence of gross contamination in the non-applicance procedures (n=81) was zero.

Albin *et al* (1992) investigated glove leak detection in a surgical and dental environment, in order to determine the frequency of perforations in latex surgical gloves (before, during, and after procedures), and also to determine the topographical distribution of perforations. Both a water pressure test and an electronic glove leak detector were used to test 679 latex surgical gloves. (The electronic glove leak detector was validated using electronic point-by-point surface probing and fluorescein dye diffusion to detect glove

punctures made with a 27-gauge needle). A leak rate of 33% (224 out of 679 gloves) was found in latex surgical gloves. The sequential surgical study demonstrated leakage in 203 out of 347 gloves (58.5%) and the sequential dental study showed 34 leaks in 106 gloves used (32.1%). With double gloving the leak rate decreased to 25% (13 of 52 gloves tested). Whilst the allowable (FDA) defect rate for unused latex surgical gloves is 1.5%, they noted defect rates in unused latex gloves of 5.5% in the sequential surgical study, 1.9% in the sequential dental study, and 4% in their electronic glove leak detector validating study.

Greco *et al* (1993) determined the risk of blood contact through surgical gloves in plastic surgical procedures. One hundred pairs of latex gloves from consecutive surgical operations were examined. All procedures were elective and performed by one attending surgeon and one of four residents. All members of the scrub team were right-handed. The gloves (surgeon = 60, assistant = 40) were collected and tested for holes by overfilling them with water and squeezing each finger and the palm individually, looking for drops or a spray of water to indicate a perforation. The perforation rate for surgeons was 38.3% compared to 22.5% for assistants. The left index finger was the most common site of perforation

(44% of perforations). Twenty nine of the 32 holes (90.6%) were in cases that lasted more than 2 hours. They recommended changing gloves at intervals under two hours and reinforcing the non-dominant index finger component of the glove for the surgeon. Others have suggested the use of a thimble on the left index finger when operating on HIV-positive patients (Maffulli 1989).

Failure of gloves and other protective devices to prevent transmission of hepatitis B virus (HBV) to oral surgeons was studied by Reingold *et al* (1988). A survey of 434 oral surgeons was carried out, noting variables such as number of years in practice, number of patients seen annually, HBV infection, and use of different protective devices. There was a strong correlation between years in practice and seropositivity, which was unaffected by reported use of gloves, face masks, or eye shields. The use of gloves and other protective devices did not appear to offer substantial protection against HBV exposure to oral surgeons and it was recommended that all oral surgeons receive HBV vaccine.

Examination gloves as barriers to hand contamination in clinical practice was studied by Olsen *et al* (1993) in order to test the effectiveness of vinyl and latex gloves as barriers to hand contamination with gram-negative organisms and

enterococci during routine hospital procedures in which exposure to these organisms on the exterior glove surface was anticipated. Gram-negative bacteria and enterococci were specifically selected for this study because they are important nosocomial pathogens and also because they could be readily differentiated from the normal microbial flora of the hand. During patient care encounters in which large numbers of bacteria were present on the external surface, gloves afforded protection against hand contamination 87% of the time. In the 11 exposure episodes in which hand contamination occurred, the organisms on the exterior surface of the glove were found on health care workers' (HCWs') hands in greatly reduced quantities. Typically, there was a 2- to 4- log reduction between the qualitative counts found on the glove surface and those found on HCWs' hands. Under the conditions during the study, leaks were detected in nearly half (43%) of the vinyl gloves tested after use but were infrequent when latex gloves were used. This study suggested that higher standards of glove production were needed to ensure that gloves in fact serve their intended purpose. Despite more frequent leaks, personnel preferred to use the vinyl gloves in many instances because they were powderless and did not irritate their skin as often as the powdered latex gloves, or because they allowed for easier manipulation of adhesive tape (by the

respiratory therapists). Interestingly, HCWs reported tears in only seven (22%) of the 32 gloves with leaks and were unaware of the other instances in which the glove leaked. These results indicate that the absence of visible leaks cannot be used by HCWs to assume glove integrity.

1.5 Multiple Gloving Studies

Recently, double-gloving has been shown to reduce contamination of the operator's hands to blood and body fluids by up to 60% (Berridge *et al* 1994; Matta *et al* 1988; Dodds *et al* 1990; Chan and Lewis 1989; Ralnay 1990). Chan and Lewis (1989) showed, in a study of single versus double gloving for gynaecologic surgery, that the perforation rate (revealed by presence of visible blood on the surgeon's hands) was 38% for single gloves (n=42) compared to 2% for double gloves (n=48). McCue *et al* (1981) showed that more perforations occurred in the outer gloves during orthopaedic procedures, and recommended periodic change of the outer gloves. Geberding *et al* (1990) showed double gloving reduced the risk of inner glove perforation by more than 60% for a wide variety of operations. Double gloving has also been compared to triple gloving, triple gloving with a stainless steel

liner and triple gloving with a kevlar liner by Schwimmer (1995).

Chiu *et al* (1993) studied the use of double latex gloves during 120 hip fracture operations, in order to determine the perforation rate of surgical gloves when double-gloving techniques were implemented. Double latex gloves were used for all operations, and all gloves were tested for perforation by water inflation. Perforation of gloves was observed in 30 operations (25%). The surgeons recognised the perforations during five operations, due to needle prick or contact with sharp instruments. The remainder of the perforations went unrecognised and were only detected by the water inflation test after surgery. In 19 cases, only the outer gloves were perforated, 10 cases had perforations involving both the outer and inner gloves, and in one case a perforation of only the inner glove was observed. A total of 64 perforation sites were identified. Forty-one perforations occurred on the left hand and 23 perforations occurred on the right hand glove. There were 48 outer glove perforations and 16 inner glove perforations. It was concluded that the glove perforation rate could be reduced by half if additional protection were applied to just the thumb and index finger of the surgeon's non-dominant hand. This protection may be achieved by a laceration-resistant layer incorporated over the outer surgical

glove. Another proposed protective method was to sandwich (between inner and outer gloves) the finger parts of an additional latex glove on the thumb and index finger of the non dominant hand.

Gloves from 280 orthopaedic operations for trauma were tested for perforation by McLeod (1989). A total of 777 pairs of surgical gloves used by orthopaedic surgeons and scrub nurses in 280 operations in the operating theatre of the trauma unit were tested. Surgeons had used 189 single and 91 double pairs of gloves. Scrub nurses used 154 single and 126 double pairs of gloves. Perforations were identified by a water inflation test. A total of 1554 gloves was examined. In total, 89 gloves were found to be perforated (66 worn by surgeons, 23 by scrub nurses). Fifty three of these perforations had been perceived by the wearer; this usually indicated that the skin had been punctured. Sixty of the perforations affected the right thumb or index finger. Fewer perforations were perceived when wearing double-gloves. The duration of the operation was directly related to the likelihood of glove perforation. Seventy seven percent of the perforations occurred in operations taking more than one hour. Of 42 perforations of outer gloves, only 14 had penetrated the inner glove as well.

The effect of double gloving on frequency of glove perforation was also studied by Bennett and Duff (1991). The aim of this study was to determine the frequency of glove perforation during obstetric and gynaecologic procedures. Gloves were tested for perforation by two methods. First, the gloves were filled with air to approximately 1.5-2 times their normal capacity and then immersed in water. Escape of air bubbles from the glove indicated perforation. Secondly, the gloves were filled with water and perforation was identified by jets of water escaping from the glove. Four hundred and forty one sets of double gloves were tested. Sixty one sets (14%, 95% confidence interval 10.8-17.2%) had a hole in at least one of the four gloves. Of 67 individual glove holes, 52 occurred only in the outer glove and 9 occurred in the inner glove. There was penetration of both gloves with matching holes in 6 instances, representing 9% of the total number of holes and 1.4% of the gloves. The observed difference in frequency of damage to outer versus inner gloves was significant ($p < 0.01$).

The efficacy of double versus single gloving was studied by Gani (1990). Double-glove perforation rates and perforation rates in standard single-gloved operating teams were compared. All gloves worn during the operation were tested for perforation by water-filling. One hundred and fifteen single-gloved operations and 103 double-gloved operations

team member involvements in procedures. In the single-glove group, 20.8% of individuals had perforations, but in the double glove group only 2.5% had perforations in both inner and outer gloves. The surgeon was most at risk of glove perforation, followed by the scrub nurse and then the first assistant. The index finger of the non-dominant hand was the most frequent perforation site amongst surgeons, and first assistants most frequently perforated the thumb of the non-dominant hand.

McCue *et al* (1981) investigated the efficacy of double-gloving during total joint arthroplasty. Gloves were tested by filling them with water, applying pressure, and observing them for leaks. Unused gloves, fresh from their sterile packages, were similarly tested for leaks. Of the 40 unused sterile gloves, no colonies were grown on culture and no holes were found. Of the 275 gloves tested after surgery, 196 were outer (firstly for draping, then a second outer pair for the procedure) and 79 were inner gloves. Of the 196 outer gloves, 26 gloves (13%) had 35 holes, but the contaminated gloves were often those used for draping. Of the 79 inner gloves, 10 (13%) had 12 holes. The authors suggest using a separate pair of outer gloves for draping to reduce glove contamination. In only three instances did the position of a hole in the glove correspond to the position of a colony. In no instance did an inner glove from whose imprint colonies grew have detected holes. Gloves worn by surgeons had 25 holes, the first

assistant's gloves had 9 holes, the second assistant's gloves had 6 holes, and the scrub nurse's gloves had 7 holes.

The rate of glove perforation when using double gloving techniques during orthopaedic surgery was examined by Saunders *et al* (1990). They examined two groups, with 50 gloves evaluated in each group via a water filling technique. Group I wore outer and inner latex gloves and group II wore outer cloth and inner latex gloves. Group I clearly had a greater number of inner glove perforations than group II. It should be noted that all surgeons in group II stated that sensibility of the hands and fingers was altered, but they had no difficulty performing the operative tasks.

The frequency of glove perforation during caesarean section delivery was studied by Yancey *et al* (1994). The study was performed for 25 women having scheduled or unscheduled caesarean delivery. Surgeons double-gloved for all procedures. Immediately after delivery, the dorsal aspect of the fingers and hand of the surgeon's outer glove was swabbed with cotton tip applicators and cultured for aerobic and anaerobic organisms. Nine of 25 cultures performed immediately before foetal extraction were positive for staphylococci. No other organisms were isolated. Cultures

performed following foetal extraction showed non-staphylococcal bacteria in 11 of 14 labouring women and one of 11 non-laboring women, a statistically significant difference ($p < 0.01$). In the labouring patients, non-staphylococcal bacteria were isolated with similar frequency from the dorsal aspect of the hand and the fingers.

1.6 Glove Construction and Structure

Virtually all brands of surgical gloves are manufactured from compounded natural rubber latex concentrate, synthetic latex or a rubber solution. Surgical gloves are constructed in one piece and are free of seams. The cuffs of these gloves are constructed in a way that resist rolling back during use. Inspection methods during manufacture must minimise the incidence of manufacturing defects such as latex drips, coagulum, visible imperfections and foreign matter. Many studies have shown that latex surgical gloves will act as an effective barrier only if the gloves remain intact and not saturated with fluid. Microscopic views of latex gloves show a semi-permeable membrane with pits 3-15 microns wide and up to 30 microns deep. Freeze-fractured sections of all gloves show cavities throughout the matrix (Arnolds and Whitman,

1988). Therefore the glove membrane has sponge-like characteristics rather than being an impervious homogeneous barrier.

There are two explanations for why surgical gloves fail:

* Mechanical stress which leads to punctures.

* Fluid saturation.

Fluid saturation is not well known to glove users. When a glove is exposed to blood or body fluids, the latex starts to hydrate which causes a decrease in its electrical resistance Richmond *et al* (1992). Because latex gloves exhibit qualities similar to those of a sponge, saturation of pores with fluid will generate a fluid bridge across the latex membrane. These fluid bridges create the potential for micro-organisms to pass through the latex membrane. Pathogenic micro-organisms and viruses are small enough to pass through latex gloves.

2. MATERIALS AND METHODS

2.1 Types of Gloves Tested

The surgical gloves tested in this study were from two different manufacturers. Ansell produced latex surgical gloves each of which was individually tested for mechanical integrity before packing. Profeel produced latex surgical gloves from which a sample of gloves were tested from each batch manufactured (Fig 2.1).

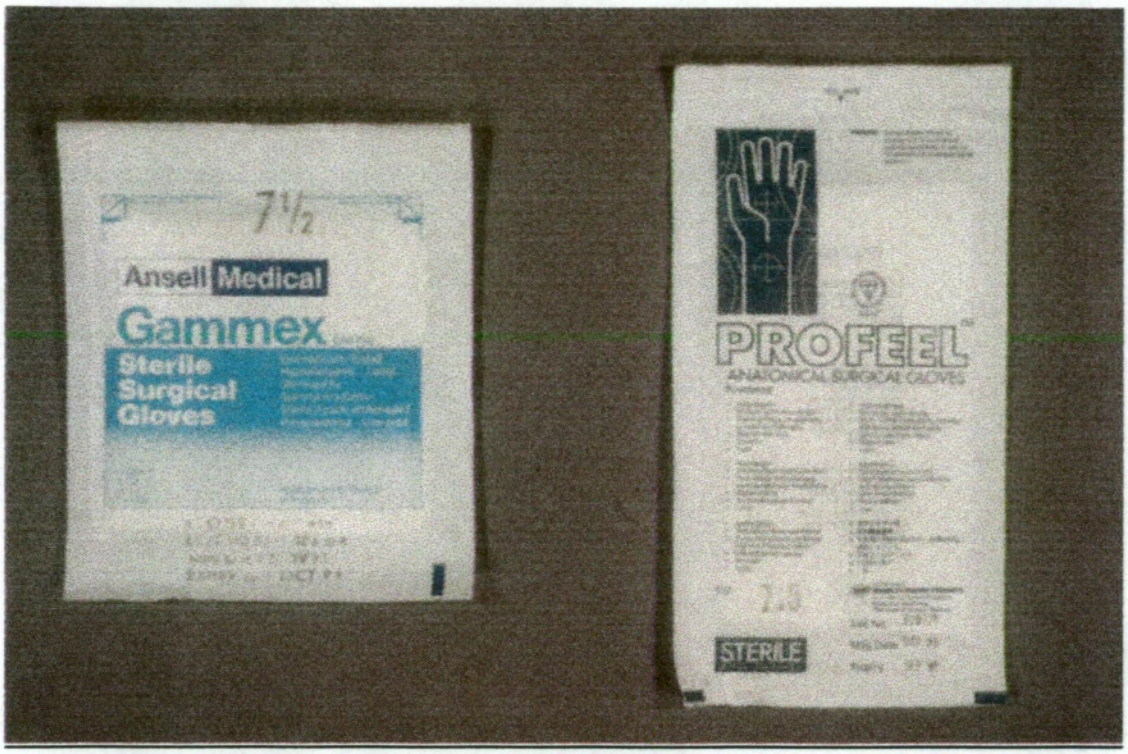


Figure 2.1: Glove Types: Gammex Ansell (individually tested for mechanical integrity), and Profeel (batch tested for mechanical integrity).

Gloves were divided according to their users as:

* Surgeon
* Assistant
* Scrub nurse.

In total, 318 Ansell Gammex gloves and 278 Profeel gloves were tested. Another unused 110 batch tested Profeel gloves and 100 Ansell individually tested gloves were tested for

perforation as controls. The glove sizes varied from 6-8 standard glove sizes. All gloves were latex rubber.

2.2 Surgical Staff, Operating Room Protocol, and Surgical Procedures

Surgical gloves worn by surgical staff were collected from 98 surgical procedures carried out at the Royal Hobart Hospital. Standardised aseptic techniques were used in all operations. The surgical team scrubbed their hands and forearms with povidone-iodine surgical scrub solution, rinsed their hands well and dried their hands with a sterile towel before gloving. Each patient's operation site was 'prepped' with povidone-iodine solution immediately prior to draping and the commencement of the surgery. Draping was by use of sterile cotton surgical drapes overlaid by a sterile adhesive plastic drape.

At the completion of surgery, for each participant, an imprint was taken of the 5 gloved fingertips of each hand on blood agar plates, and then the 5 gloved fingertips were washed in

soya broth, Gloves were then removed so as not to contaminate the hands with the glove exteriors. Imprints of the bare fingertips were then made on blood-agar and then bare fingertips were washed in soya broth (see 2.5 for more detail on glove collection).

Gloves used by surgeons (main surgeon and assistant) and nursing staff were collected at the completion of each operation. In cases where a hole developed and was detected during surgery by the scrub team, the wearer was expected to follow standard operating room procedure and replace the glove. In such cases the discarded glove was excluded from the study and only the gloves worn by staff at the end of surgery were tested. The types of operations included in this study are set out in Table 2.1.

Operation Type	Ansell	Profeel	Total
Thyroidectomy	10	5	15
Appendicectomy	1	0	1
Laparoscopy	2	0	2
Minor General Ops.	24	12	36
Parathyroidectomy	3	1	4
Varicose Veins	1	3	4
Major Breast/Axilla	3	3	6
Inguinal Hernia	7	9	16
Breast Biopsy	6	14	20
Cholecystectomy	4	1	5
Minor Orthopaedic	1	3	4
Total operations for each glove type	62	51	113
Less operations in which Ansell or Profeel gloves were worn by different team members (see shaded rows Table 3.3)			-14
Less 1 for misnumbering (ie note from Table 3.3 - no operation number 50			-1
Total Operations			98

Table 2.1: Types of operations assessed in the glove study.

2.3 Controls for Pre-existing Mechanical Integrity

Because of the sterility of the gloves prior to surgery, gloves could not be tested before operative use. To establish a baseline or control perforation rate, 110 pairs of unused Ansell individually tested gloves and 110 pairs of unused Profeel batch tested gloves of various sizes, from the same lots as the study gloves, were tested for pre-existing perforation.

2.4 Methods for Glove Testing

Recognising that different tests of mechanical integrity have different sensitivities, gloves were tested using two different methods:

1) Water jet method;

2) Electrical resistance method.

In the water jet test method, each glove was filled with water at room temperature to the cuff and suspended whilst a visual inspection was made for leaks (Fig 2.2A).

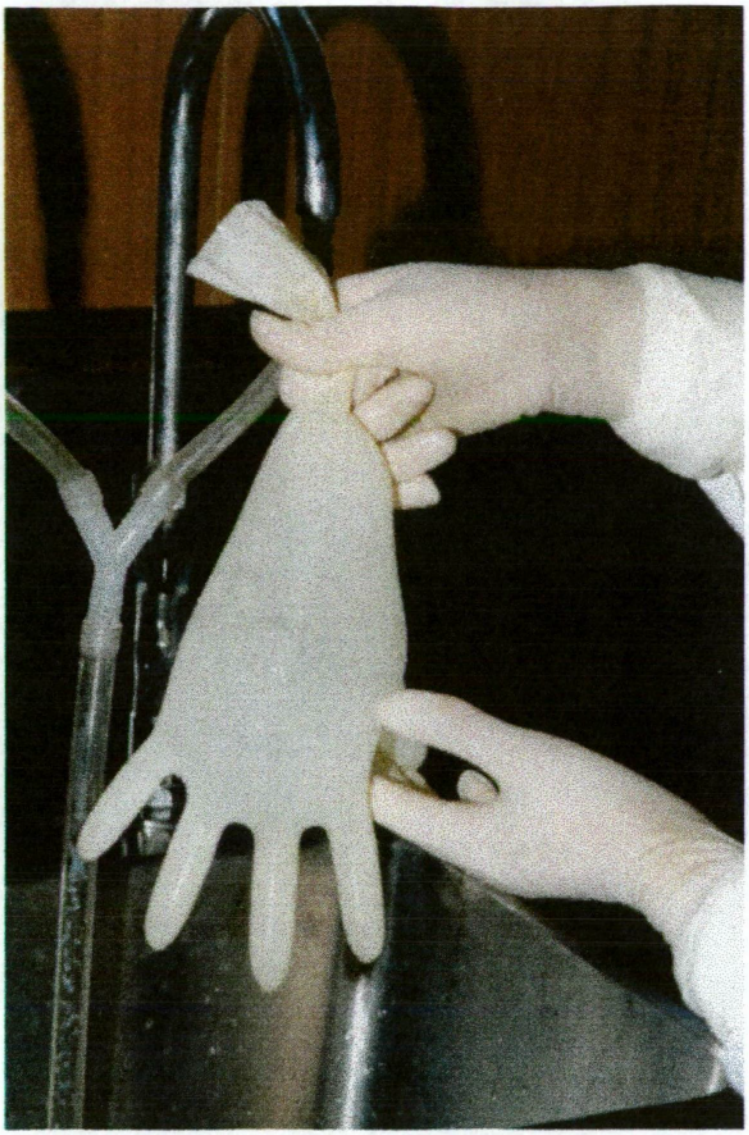
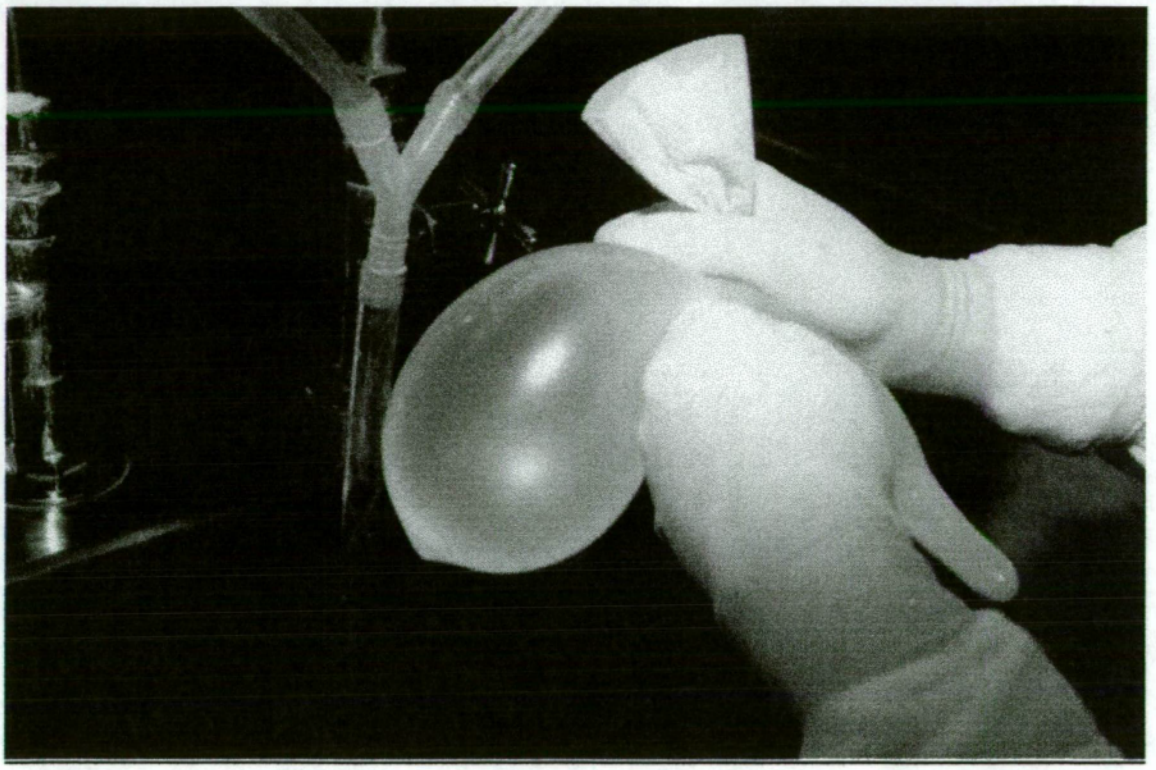


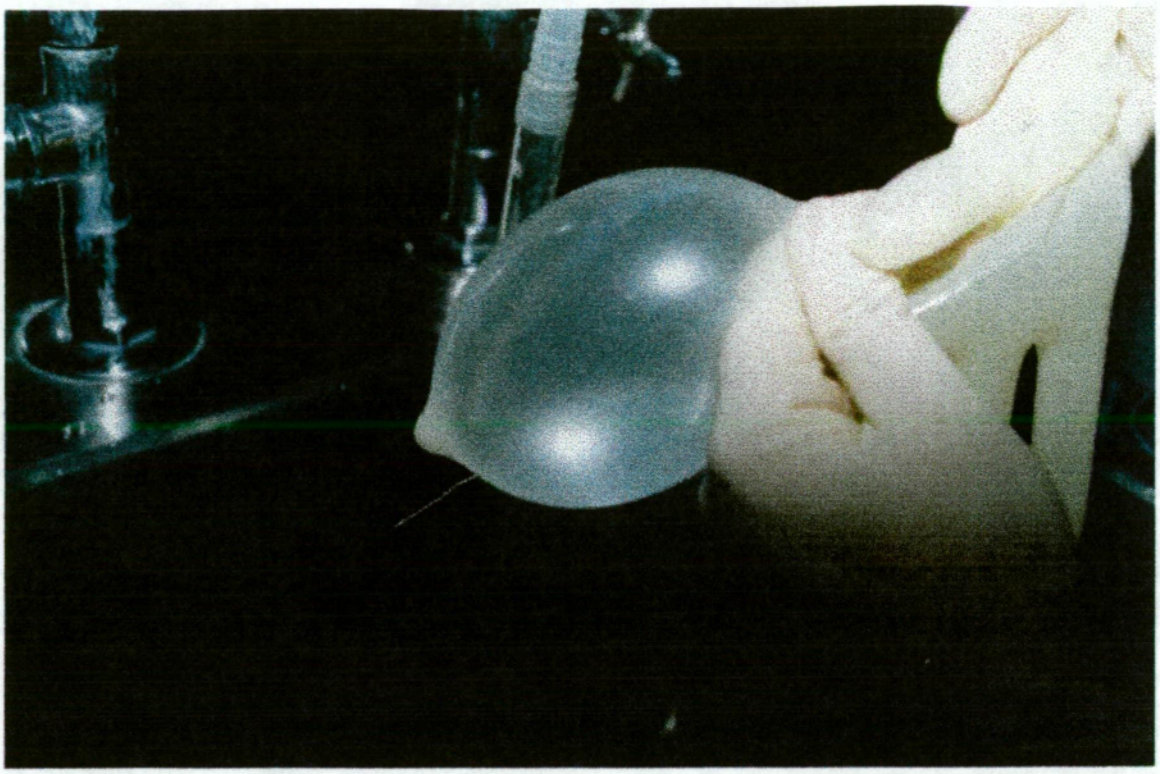
Figure 2.2A: Mechanical glove testing. Each glove was filled to the cuff and suspended for a visual inspection for leaks.

After 2 minutes, each glove was twisted at the cuff through 360° to seal the cuff. Each part of the glove was then compressed externally and ballooned out, and inspected for

leaks (Fig. 2.3A and 2.3B). The amount of water placed into each glove averaged 300 ml, but varied ±25 ml depending on the size of the glove.



2.3A. No perforation



2.3B. Perforation

Figure 2.3 Each glove was filled with water to the cuff and twisted through 360°. Each part of the glove was then externally compressed whilst a visual inspection was performed for leaks (A: no leaks; B: example of observed leak).

The electrical resistance test method consisted of placing each glove, filled with saline 9% (w/v), into a tank also filled with 9% saline, and measuring the electric current between the inside and outside of the glove with an ammeter (Fig. 2.4). The electrical resistance across the glove was high in non-perforated gloves. However if the glove was punctured, the

electrical resistance was significantly lower indicating current flow, thus providing a way of demonstrating the presence of a pinhole (Fig. 2.5A and 2.5B).

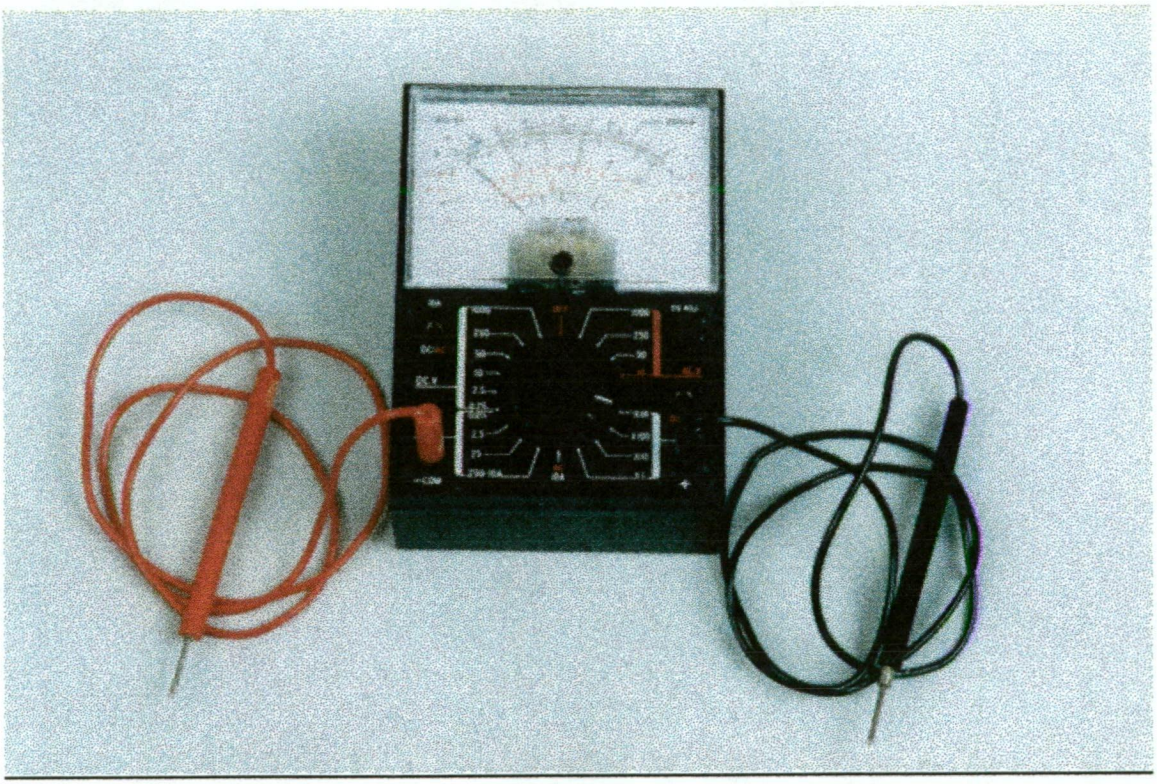
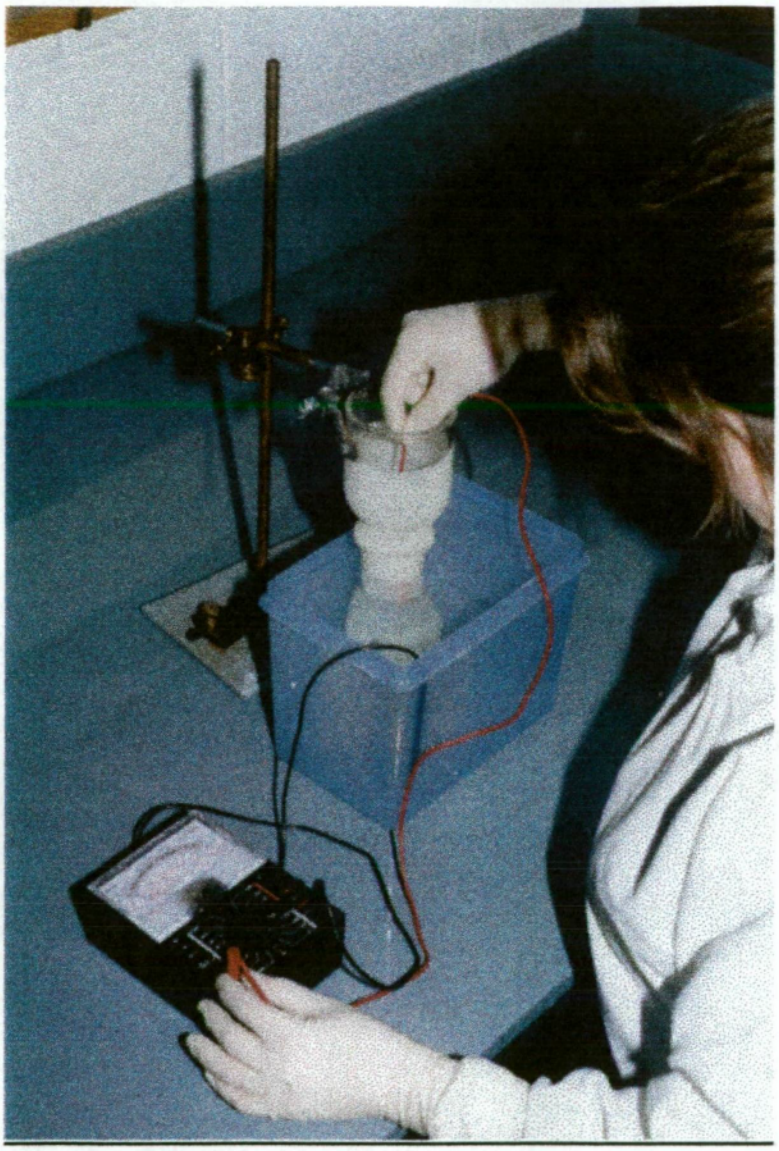
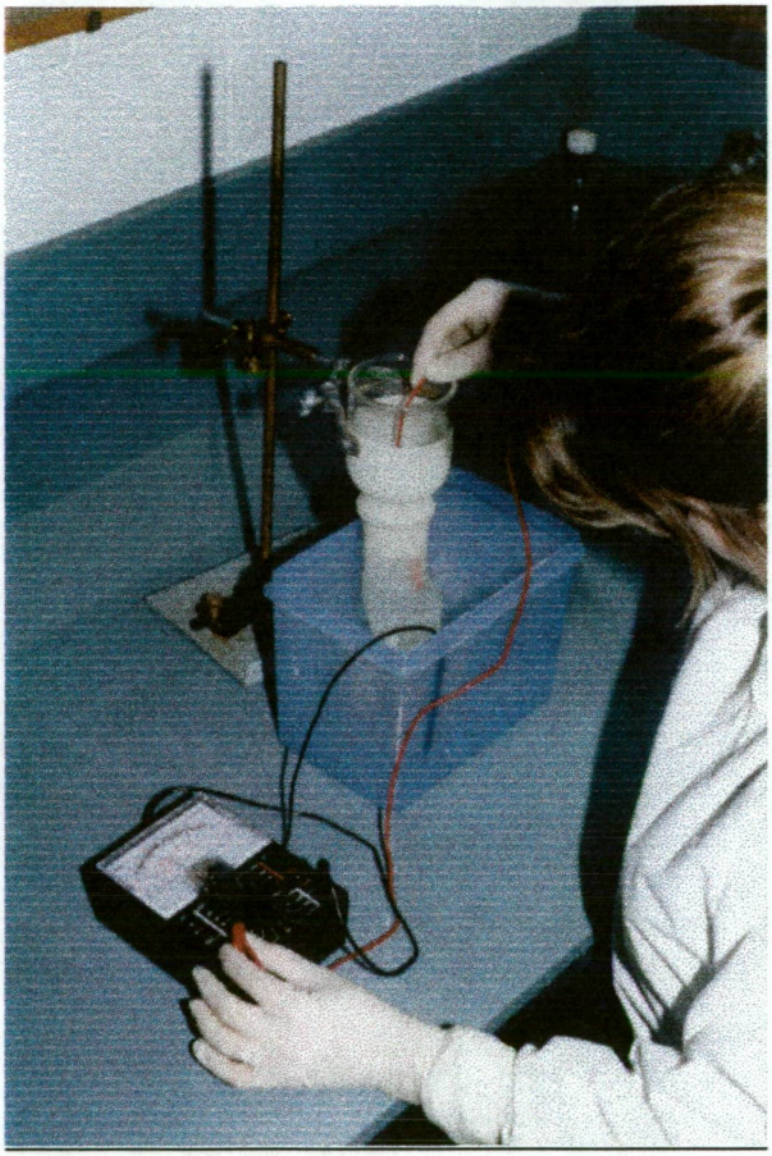


Figure 2.4: Ammeter used to detect holes in the gloves.



2.5A: No perforation.



2.5B. Perforation

Figure 2.5: Electrical test method: each glove was immersed and filled with 0.9% saline. The negative probe was placed inside the glove and positive probe outside the glove. If a perforation was present, the electrical circuit would be completed and would register current flow on the ammeter.

2.5 Collection of Gloves

At the completion of each operation, imprints of the gloved fingers were made on horse blood agar plates (Fig. 2.6), and the gloved fingers immersed in culture broth (Fig. 2.7). Agar plates and broth cultures were incubated for 24h at 37C°.

Figure 2.6: Glove printing on horse blood agar following surgical operations were incubated for 24 hours at 37°C.

Figure 2.7: Surgeon's glove washed in (200ml) tryptone soya broth following operation.

Gloves were then removed by each scrub team member in a sterile fashion and placed in sterile bags labelled with the type of surgery, the identity of the scrub-team member, the right or left side, and type of glove (Fig 2.8: A, B, C).

Figure 2.8A.

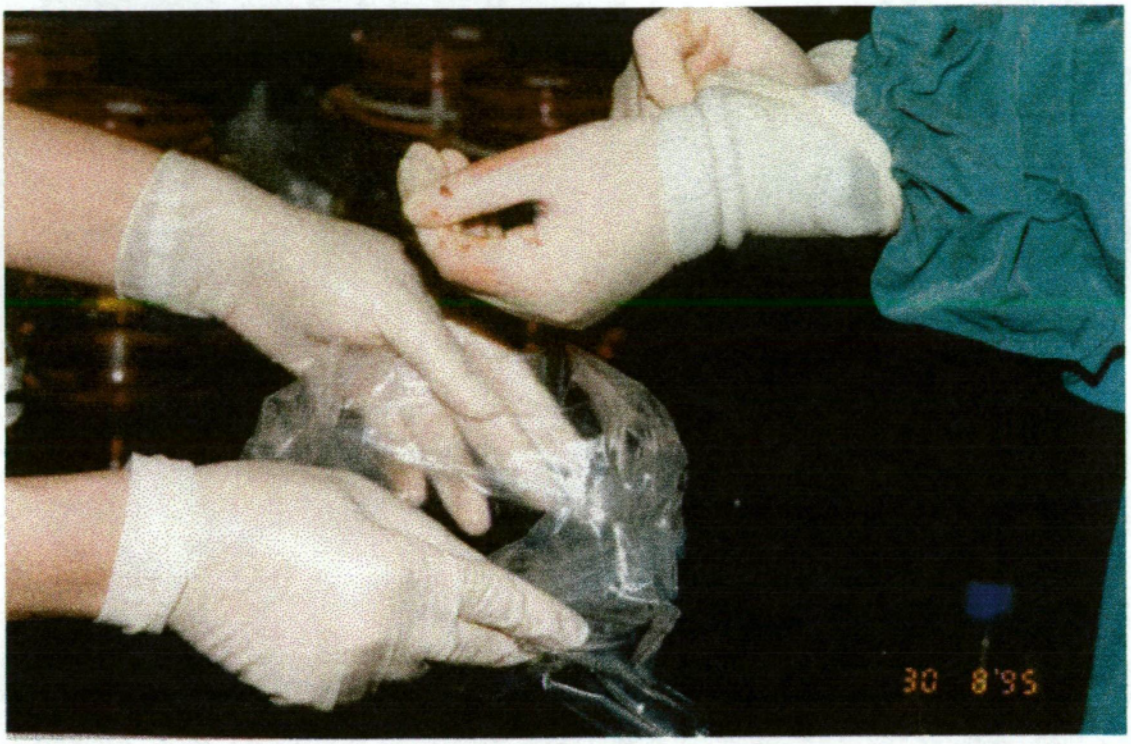


Figure 2.8B.

Figure 2.8C.

Figure 2.8: Sterile removal of gloves for perforation testing following operation.

Immediately upon removal and bagging of the gloves, the scrub team's fingers were then imprinted onto Horse Blood Agar plates (Fig. 2.9), and then immersed in culture medium (Tryptone Soya Broth) (Fig. 2.10).

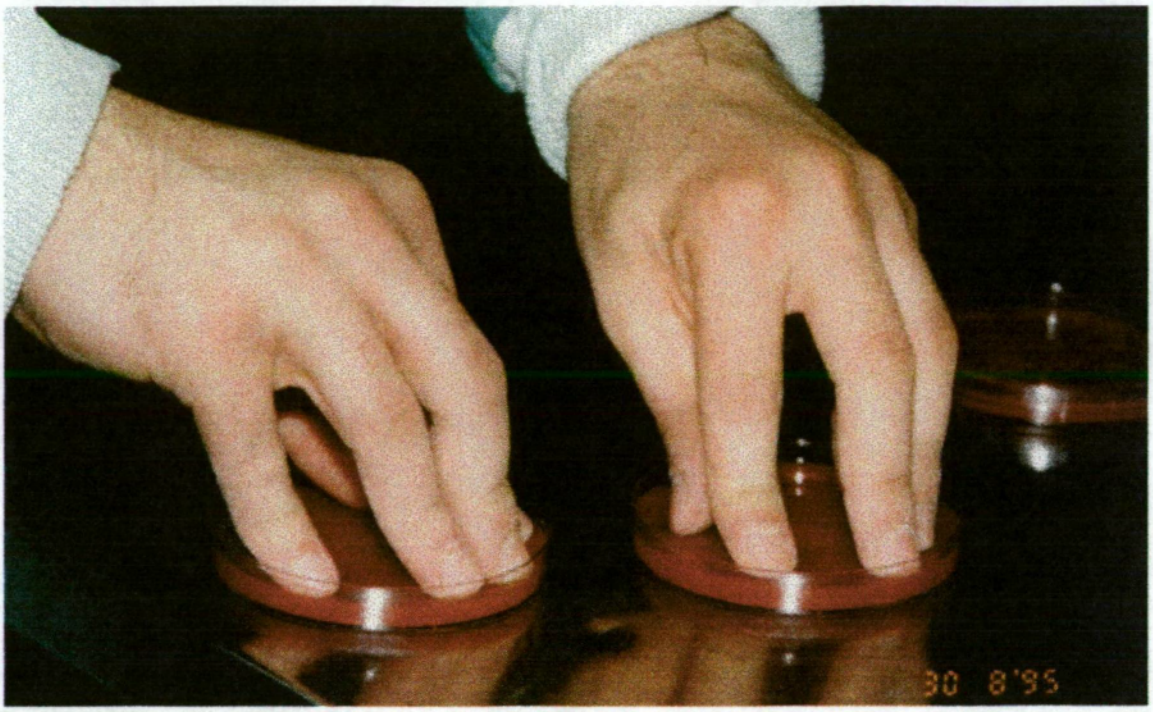


Figure 2.9 : Finger printing of surgeon's hands following operation on horse blood agar.

Figure 2.10: Nurse's hand washed in tryptone soya broth (200ml) following operation.

3.0 RESULTS

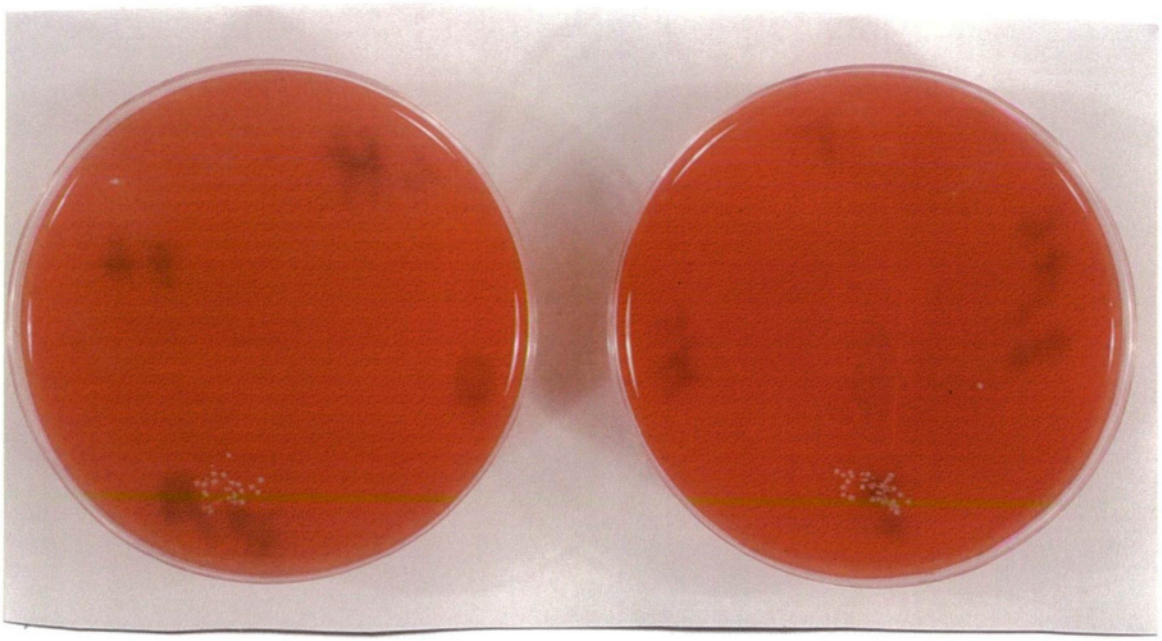
3.1 Bacteriologic Analysis

Microbial analysis of gloves and hands of all theatre staff {surgeon (1 and 2), assistant (1 and 2) and scrub nurse (1 and 2)} following surgical procedures, by imprinting fingers onto horse blood agar plates and incubation for 24h at 37°C, showed that the majority of gloves were contaminated with microbial flora. However, the bacteria present were part of the normal skin flora of the wearer and not implicated in wound infection (Fig 3.1).

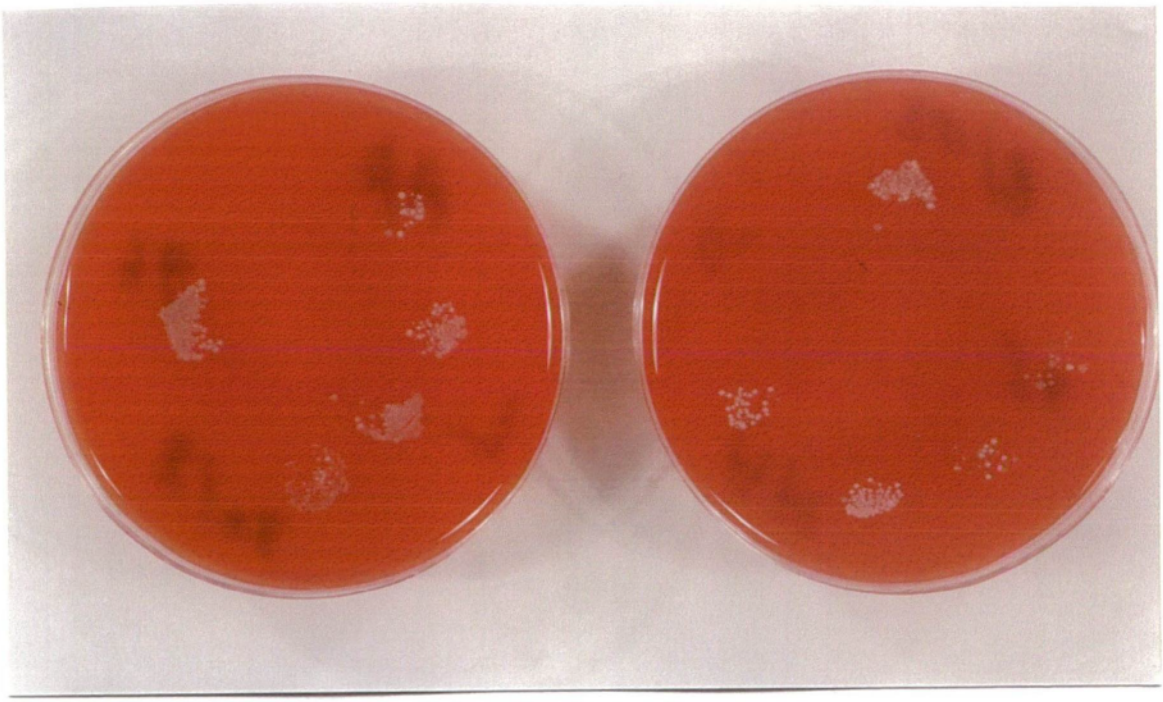
Microbial analysis of gloves following surgical procedures, by washing gloves and hands in tryptone soya broth similarly showed that the majority of gloves were contaminated with microbial flora. Again, the bacteria present were part of the normal skin flora of the wearers and were not implicated in wound infection (Fig. 3.2).

Microbial analysis of the hands of theatre staff (surgeon, assistant and scrub nurse) following surgical procedures, by finger imprinting onto horse blood agar plates and incubation for 24h at 37°C showed that the staff hands were covered with high levels of normal microbial flora by the end of the

procedures, the same bacteria as found in lower levels on the outside of the gloves. There was no difference in microbial contamination between staff using Ansell (individually tested gloves) and Profeel (batch tested gloves) (Fig. 3.4). Microbial analysis of hands of theatre staff (surgeon, assistant and scrub nurse) following surgical procedures by washing hands in tryptone soya broth gave similar results (Fig. 3.5).



A. Assistant's right and left hand prints after surgery



B. Nurse's right and left hand prints after surgery

Figure 3.1: Bacterial growth on horse blood agar incubated for 24h at 37°C

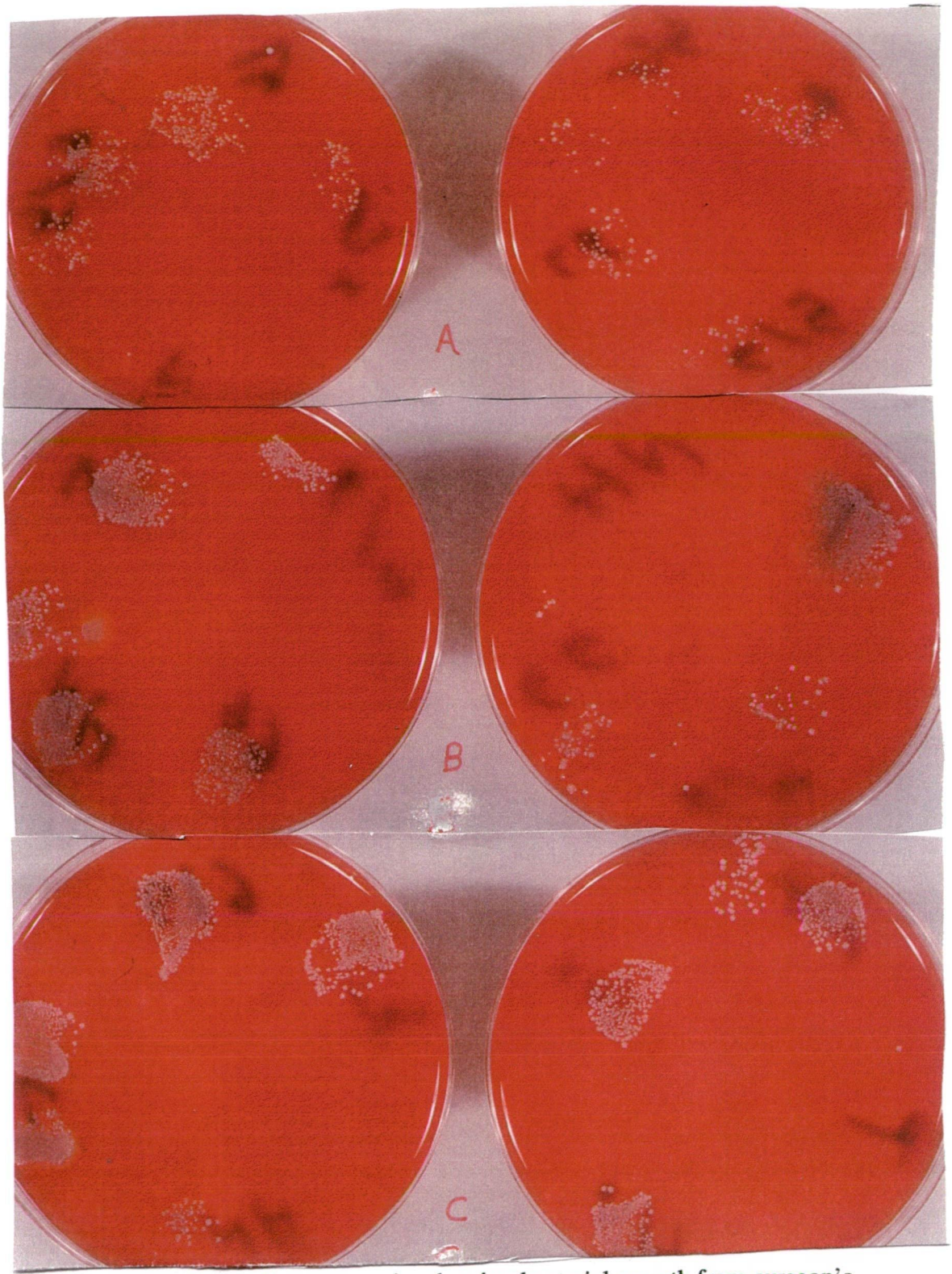
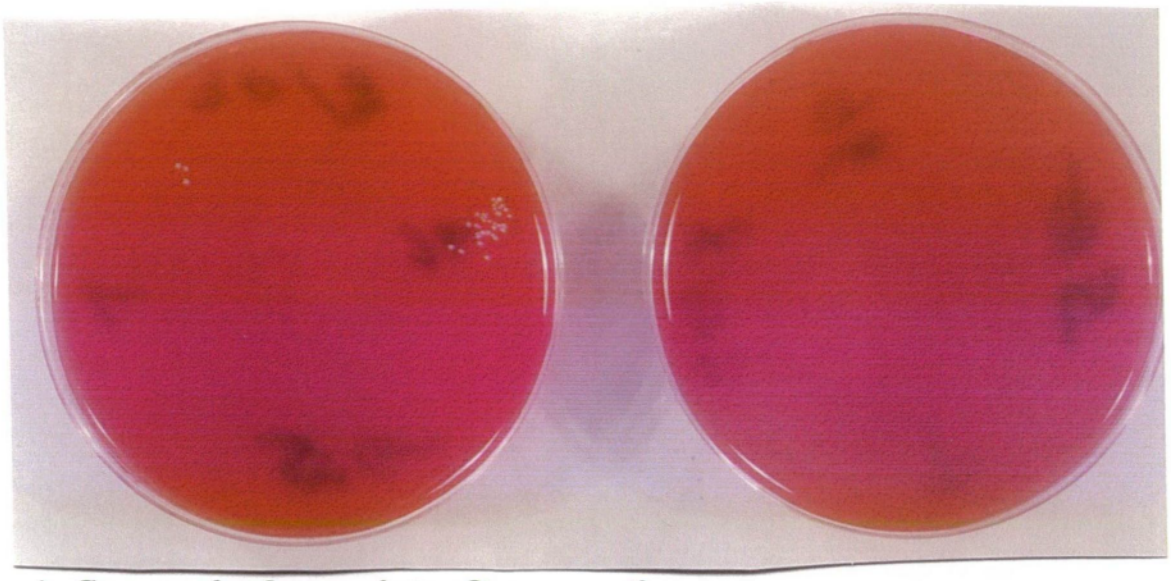
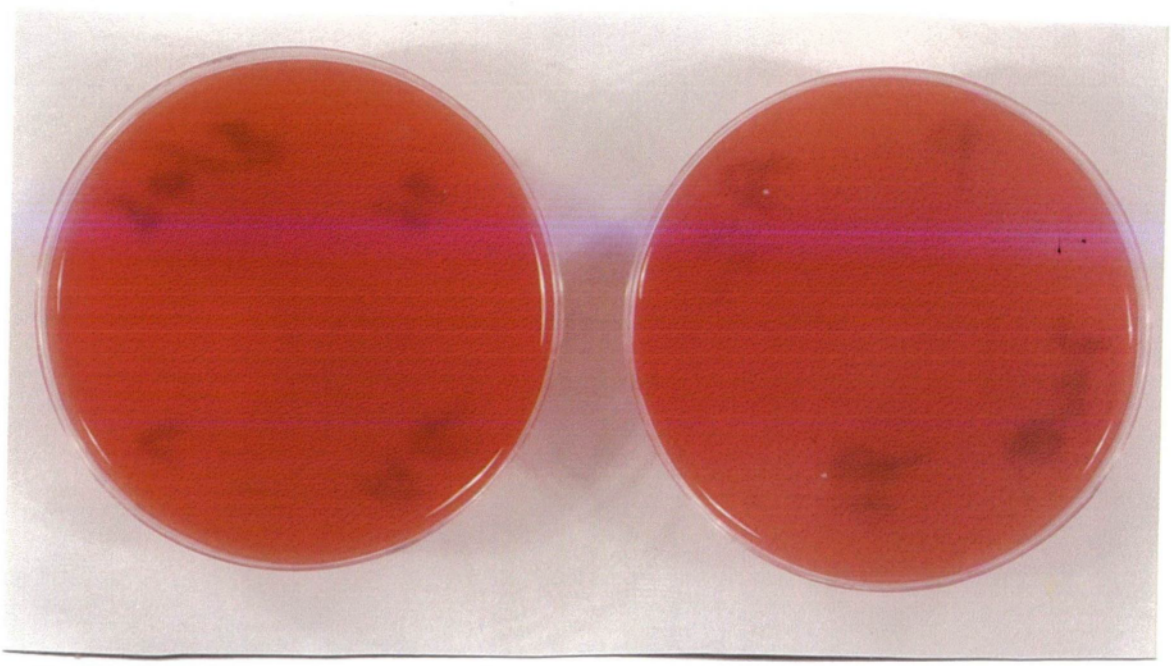


Figure 3.2(A,B,C): Three examples showing bacterial growth from surgeon's hands after operation, following incubation on horse blood agar for 24h at 37°C.



A: Surgeon's glove prints after operation



B: Assistant's glove prints after operation

Figure 3.3(A,B): Bacterial growth on horse blood agar incubated for 24h at 37°C.

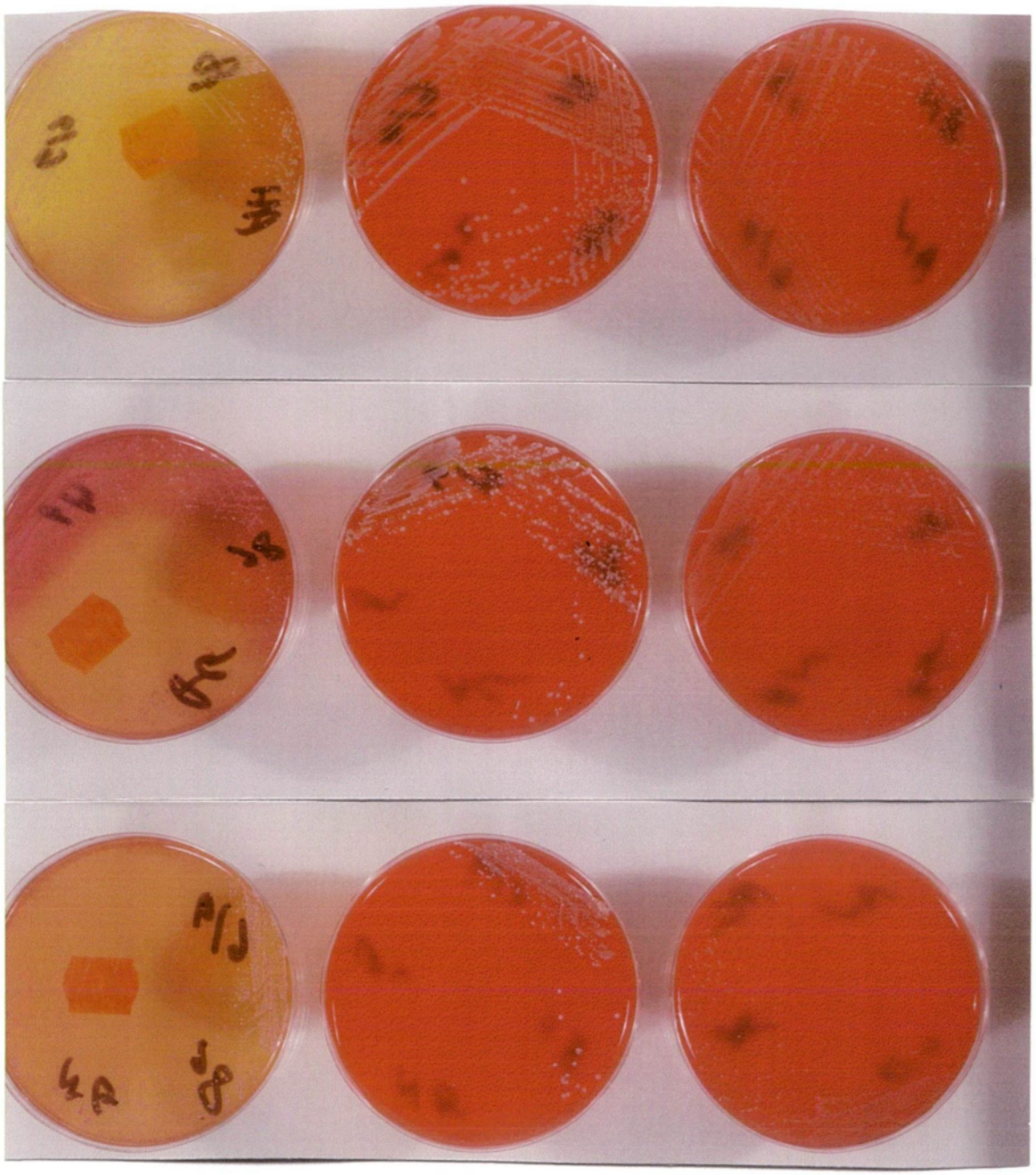


Figure 3.4: Bacterial growth from tryptone soya broth plated onto two plates of horse blood agar (one incubated in humidified 95% oxygen/5% CO_2 and the other in an anaerobic atmosphere), and a third sample plated onto MacConkey agar, all incubated for 37°C for 24h.

Addition to page 62:

MacConkey agar: left plates
Horse blood agar (95% O_2/5% CO_2): central plates
Horse blood agar (anaerobic): right plates

Horse blood agar is a general medium which supports growth of most common bacteria. Anaerobic growth was used to detect growth of anaerobic bacteria. MacConkey agar is a more selective medium (containing bile salts and lactose) which inhibits overgrowth of common bacteria, especially coliforms and proteus, and allows easier identification of individual bacterial types

Addition inder legend of Figure 3.5 page 63:

Clouded broth on left indicates bacterial growth

Note under legend of Table 3.4 (1st section only) page 67:

Note: Column 6 should be headed: Hand Plates, R,L.

Figure 3.5: Bacterial growth after 24h at 37°C in tryptone soya broth (200ml) following operation.

3.2 Glove Perforations

3.2.1 Baseline Frequency of Perforations in Unused Gloves

The results for testing of unused gloves from each brand showed that of 110 pairs of Profeel gloves, one glove contained a detectable perforation, and of 110 pairs of Ansell gloves there were zero perforations. By Chi squared analysis, this difference is not statistically significant. The potential clinical significance is discussed in Section 4.

3.2.2 Glove Perforation Rates Following Surgery

Comparison of glove perforations between Ansell (individually tested gloves) and Profeel (batch tested gloves) is shown in summary form in Table 3.1. The raw data is shown in Table 3.4, where associations can be seen between individual cases of glove perforation and microbial culture findings. The results show that Profeel gloves had a significantly lower number of perforations than Ansell gloves at the end of the procedures. Chi squared analysis is set out below in Tables 3.2 and 3.3.

Glove Type	Perforation (No. gloves)	No Perforation (No. gloves)	Total (No. gloves)
Ansell	22	282	304
Profeel	8	274	282
Total	30	556	586

Table 3.1: Summary of glove perforations found by either water-jet or electrical test methods following surgery.

Test = Chi-squared test of independent proportions:

Is (22/304) significantly different from (8/282) ?

Glove Type	Perforation	No Perforation	Total
Ansell	304/586 x 30 =15.563	304/586 x 556 =288.437	304
Profeel	282/586 x 30 =14.437	282/586 x 556 =267.563	282
Total	30	556	586

Table 3.2: Calculation of expected numbers of perforations assuming the null hypothesis for Chi squared analysis.

Glove Type	Perforation	No Perforation
Ansell	22-15.563 = 6.437	280-288.437 = -8.437
Profeel	8-14.437 = -6.437	271-267.563 = 3.437

Table 3.3: Calculation of observed (O) minus expected (E) numbers of perforations for Chi squared analysis.

Chi Squared calculation:

$$X^2 = (O_1 - E_1)^2 / E_1 + (O_2 - E_2)^2 / E_2 + (O_3 - E_3)^2 / E_3 + (O_4 - E_4)^2 / E_4$$

$$X^2 = (6.437)^2/15.563 + (-8.437)^2/288.437 + (-6.437)^2/14.437 + (3.437)^2/267.563$$

$$X^2 = 2.662 + 0.246 + 2.870 + 0.044$$

$$X^2 = 5.822$$

There is strong evidence against the null hypothesis that the proportions 22/304 and 8/280 are identical (p=0.016).

Operation No.	Operation	Team Member	Glove Type	Glove Plates R,L	Hand Swabs Bacteria,R,L	Glove Broth	Hand Broth	Perf R H	Perf L H
1	Thyroidectomy	S1 (A)	ansell	clean,clean	staph epi++,+++	staph epi &aure	staph epi	N	N
1	Thyroidectomy	A1	ansell	clean,clean	staph epi++,+++	clean	staph epi	N	N
1	Thyroidectomy	N1	ansell	clean,clean	staph epi++,+++	staph epi	staph epi	N	N
2	Appendicectomy	S1 (D)	ansell	clean,clean	staph epi++,+++	staph epi	staph epi	N	N
2	Appendicectomy	A1	ansell	clean,clean	staph epi++,+++	clean	staph epi	N	N
2	Appendicectomy	N1	ansell	clean,clean	staph epi++,+++	staph epi	staph epi	N	N
3	Laparoscopy	S1 (B)	ansell	clean,clean	staph epi++,+++	clean	clean	Y	N
3	Laparoscopy	A1	ansell	clean,clean	staph epi++,+++	clean	clean	N	Y
3	Laparoscopy	N1	ansell	clean,clean	staph epi++,+++	clean	clean	N	N
4	Thyroidectomy	S1 (A)	ansell	clean,staph epi+	staph epi+++,+++	staph epi	staph epi	N	N
4	Thyroidectomy	A1	ansell	clean,staph epi+	staph epi+,clean	staph epi	staph epi	N	N
4	Thyroidectomy	N1	ansell	staph epi ++,clean	staph epi+++,+++	staph epi	staph epi	N	N
4	Thyroidectomy	N2	ansell	clean,clean	clean,clean	clean	clean	N	N
5	Carpal tunnel release	S1 (A)	ansell	clean,clean	staph epi +++,+++	staph epi	staph epi	N	N
5	Carpal tunnel release	A1	ansell	clean,clean	staph epi ++,++	clean	staph epi	N	N
5	Carpal tunnel release	N1	ansell	clean,clean	staph epi +++,+++	staph epi &aure	staph epi	N	N
6	Ing. hernia	S1 (A)	ansell	staph epi +,clean	staph epi +++,+++	staph epi	staph epi	N	N
6	Ing. hernia	A1	ansell	clean,clean	staph epi +++,+	clean	staph epi	N	N
6	Ing. hernia	N1	ansell	clean,clean	staph epi++,+++	clean	staph epi	N	N
7	Parathyroidectomy	S1 (C)	ansell	staph epi++,++	staph epi++,+++	staph epi	staph epi	N	N
7	Parathyroidectomy	A1	ansell	staph epi++,+++	staph epi++,+++	clean	staph epi	N	Y
7	Parathyroidectomy	N1	ansell	clean,clean	staph epi++,+++	staph epi	staph epi	N	N

Table 3.4: *(Sheet 1)* : The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations). Cases in which both Ansell and Profeel gloves were worn by different team members are shaded yellow. The code letter for the primary surgeon (S1) is given in brackets.

Operation No	Operation	Team Member	Glove Type	Glove Plates R,L	Hand Swabs Bacteria R,L	Glove Broth	Hand Broth	Perf R H	Perf L H
8	Laparoscopy	S1 (B)	ansell	staph epi+,aur+	clean,staph epi+	staph epi	staph epi	N	N
9	Ing. hernia	S1 (D)	ansell	staph epi+,+	clean,clean	staph epi	staph epi	N	N
9	Ing. hernia	A1	ansell	clean,clean	staph epi+,+	staph epi	staph epi	N	N
9	Ing. hernia	N1	ansell	clean,clean	staph epi++,++	staph epi	staph epi	N	N
10	High lig. var. veins	S1 (D)	ansell	clean,clean	staph epi+,+	staph epi	staph epi	Y	N
10	High lig. var. veins	A1	ansell	staph epi+,clean	staph epi+,+	staph epi	staph epi	N	N
10	High lig. var. veins	N1	ansell	clean,clean	staph epi+,+	clean	staph epi	N	N
11	Goitre multinodular	S1 (A)	ansell	staph epi+,++	staph epi++,++	staph epi	staph epi	N	N
11	Goitre multinodular	S2	ansell	staph epi++,+	staph epi+,++	staph epi	staph epi	N	N
11	Goitre multinodular	N1	ansell	clean,clean	staph epi++,++	clean	staph epi	N	N
11	Goitre multinodular	A1	ansell	staph epi+,+	staph epi+,clean	staph epi	staph epi	N	N
12	Parathyroidectomy	S1 (C)	ansell	staph epi +,+	staph epi ++,+	staph epi	staph epi	N	N
12	Parathyroidectomy	A1	ansell	clean,staph epi +	staph epi +,+	staph epi	staph epi	N	N
12	Parathyroidectomy	N1	ansell	clean,clean"	staph epi ++,+++	staph epi	staph epi	N	Y
12	Parathyroidectomy	S2	ansell	staph epi +,+	staph epi ++,+++	staph epi	staph epi	N	N
14	Exc. cyst low back	S1 (E)	ansell	clean,clean	staph epi +	clean	staph epi	N	N
14	Exc. cyst low back	A1	ansell	clean,clean	staph epi +,+++	clean	staph epi	N	N
14	Exc. cyst low back	N1	ansell	clean,clean	staph epi +++,+++	stap epi	staph epi	N	N
17	Cholecyctectomy	S1 (F)	ansell	clean,clean	staph epi+++,+++	clean	staph epi	N	N
17	Cholecyctectomy	A1	ansell	clean,clean	staph epi ++,++	stap epi	staph epi &bacilles	N	N
17	Cholecyctectomy	N1	ansell	clean,clean	staph epi ++,++	stap epi	staph epi	N	N
17	Cholecyctectomy	A2	ansell	clean,clean	staph epi +,+	clean	staph epi	N	N

Table 3.4: *(Sheet 2)* : The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations). Cases in which both Ansell and Profeel gloves were worn by different tam members are shaded yellow. The code letter for the primary surgeon (S1) is given in brackets.

Operation No	Operation	Team Member	Glove Type	Glove Plates R,L	Hand Swabs Bacteria,R,L	Glove Broth	Hand Broth	Perf R H	Perf L H
18	Breast biopsy	S1 (F)	ansell	staph epi +,+	staph epi +++,+++	staph epi & aure	staph epi	N	N
18	Breast biopsy	A1	ansell	clean,clean	staph epi +,clean	clean	staph epi	N	N
18	Breast biopsy	N1	ansell	clean,clean	staph epi +++,+++	clean	staph epi	N	N
20	Thyroidectomy	S1 (A)	ansell	staph epi +,++& bacilles	staph epi ++,+++	staph epi	Staph aure	N	N
20	Thyroidectomy	A1	ansell	staph epi +,+	staph epi +,+	staph epi &bacilles	Staph epi	N	Y
20	Thyroidectomy	N1	ansell	staph epi +,+	staph epi +++,+++	staph epi	staph epi	N	N
20	Thyroidectomy	S2	ansell	staph epi ++,++	staph epi +++,+++	staph epi	staph epi	N	N
21	Exc. thyroid nodule	S1 (A)	ansell	clean,clean	staph epi ++,+++	clean	staph epi	N	N
21	Exc. thyroid nodule	N1	ansell	clean,clean	staph epi ++,+++	staph epi	staph epi	Y	N
24	Thyroidectomy	S1 (A)	ansell	staph epi +,clean	staph epi ++,+++	staph epi	staph aure	N	N
24	Thyroidectomy	A1	ansell	staph epi +,clean	staph epi +,++	staph epi	staph epi	N	N
24	Thyroidectomy	N1	ansell	clean,clean	staph epoi ++,+++	staph epi	staph epi	N	N
28	Ing. Hernia	S1 (G)	ansell	clean,clean	staph epi +++,+++	staph epi	staph epi	N	N
28	Ing. Hernia	N1	ansell	staph epi +,clean	staph epi++,++	staph epi	staph epi	N	N
29	Mastectomy	S1 (A)	ansell	staph epi +,+ & bacilles	staph epi +++,+++ & bacilli	staph epi	staph epi	N	N
29	Mastectomy	S2	ansell	clean,clean	staph epi ++,+++	staph epi	staph epi	Y	N
29	Mastectomy	N1	ansell	staph epi +,clean	staph epi ++++,++++	staph epi	staph epi	N	N
29	Mastectomy	S2	ansell	staph epi ++,+	staph epi ++,+++	staph epi	staph epi	N	N
31	Thyroidectomy	S1 (A)	ansell	clean,clean	staph epi++,+++	clean	stpah epi	N	N
31	Thyroidectomy	A1	ansell	clean,clean	staph epi ++,+++	staph epi	staph epi	N	N
31	Thyroidectomy	N1	ansell	clean,clean	staph epi +++,+++	clean	staph epi	N	N
31	Thyroidectomy	A2	ansell	clean,clean	staph epi ++,++	clean	staph epi	N	Y

Table 3.4: *(Sheet 3)* : The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations). Cases in which both Ansell and Profeel gloves were worn by different team members are shaded yellow. The code letter for the primary surgeon (S1) is given in brackets.

Operation No	Operation	Team Member	Glove Type	Glove Plates R,L	Hand Swabs Bacteria,R,L	Glove Broth	Hand Broth	Perf R H	Perf L H
32	Exc. lesion temple	A1	ansell	staph epi +++,+++	clean,staph epi +	staph epi	staph epi	N	N
33	Exc. two lesions scalp	S1 (H)	ansell	staph aure++++, contam.	staph epi ++,+	staph aure	staph epi	N	N
33	Exc. two lesions scalp	A2	ansell	staph aure ++++, ++++	staph epi +,+	staph aure	staph epi	N	Y
33	Exc. two lesions scalp	S2	ansell	staph aure+++, +++	staph epi ++++,++++	staph aure	staph epi	N	N
35	Int. fixation 5th metacarpal	A1	ansell	staph epi +,+	clean,clean	staph epi , aure & bacilli	staph epi	N	Y
35	Int. fixation 5th metacarpal	N1	ansell	clean,clean	staph epi +++,+++	clean	staph epi	Y	N
37	Breast lump	A1	ansell	staph epi +,+	staph epi +,+	staph epi	staph epi	N	N
37	Breast lump	N1	ansell	staph epi +,+	staph epi +,clean	clean	staph epi	N	N
38	Carp. tun. release	S1 (G)	ansell	clean,clean	staph epi +,++	clean	staph epi	N	N
38	Carp. tun. release	A1	ansell	clean,clean	clean,staph epi++	clean	staph epi	N	N
38	Carp. tun. release	N1	ansell	clean,clean	staph epi +++,++	clean	staph epi	N	N
40	Exc. BCC	S1 (I)	ansell	stpah epi ++++, ++++ & aure ++,++	staph epi ++++,++++	staph epi	staph epi	N	N
40	Exc. BCC	A1	ansell	staph epi ++,++	staph epi +,+	staph epi & bacilli	staph epi & aure	N	N
40	Exc. BCC	N1	ansell	contaminated, staph epi +++	staph epi ++++,++++	staph epi	staph epi & bacilli	N	N
40	Exc. BCC	N2	ansell	staph epi +,++	staph epi ++,+++	staph epi	staph epi	N	N

Table 3.4: ***(Sheet 4)*** : The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations). Cases in which both Ansell and Profeel gloves were worn by different team members are shaded yellow. The code letter for the primary surgeon (S1) is given in brackets.

Operation No	Operation	Team Member	Glove Type	Glove Plates R,L	Hand Swabs Bacteria,R,L	Glove Broth	Hand Broth	Perf R H	Perf L H
42	Endo carpal tunnel	S1 (H)	ansell	clean,clean	staph epi +++,++	clean	staph epi	N	N
42	Endo carpal tunnel	A1	ansell	clean,clean	staph epi +,clean	staph epi	staph epi & aure	N	N
42	Endo carpal tunnel	N1	ansell	clean,staph epi +	staph epi ++++, ++++	staph epi	staph epi	N	N
42	Endo carpal tunnel	S2	ansell	clean, contaminated	staph epi +++, contaminted	stpah epi	staph epi	N	N
43	Exc. (R) neck lipoma	S1 (J)	ansell	staph epi +,+	staph epi ++,+	staph epi	staph epi	N	N
43	Exc. (R) neck lipoma	A1	ansell	staph epi+++,++	clean,clean	staph epi	staph epi	N	N
45	Para umbilical hernia	S1 (G)	ansell	clean,clean	staph epi ++,++	clean	staph epi	N	N
45	Para umbilical hernia	A1	ansell	clean,clean	staph epi ++,++	staph epi	staph epi	N	N
45	Para umbilical hernia	N1	ansell	clean,clean	staph epi ++,+	staph epi	staph epi & aure	N	N
46	Thyroidectomy	S1 (A)	ansell	clean,clean	staph epi ++,+++	staph epi & aure	staph epi	N	N
46	Thyroidectomy	A1	ansell	staph epi +,+	staph epi +,+	clean	staph epi	N	N
46	Thyroidectomy	N1	ansell	staph epi ++,++	staph epi +++,++++	staph epi	staph epi	N	Y
46	Thyroidectomy	S2	ansell	clean,clean	staph epi +++,+++	staph epi	staph epi	N	N
47	Dupuytrens contrac.	S1 (H)	ansell	clean,clean	staph epi +++,+++	staph epi	staph epi	N	N
47	Dupuytrens contrac.	A1	ansell	clean,clean	clean,clean	staph epi	staph epi	N	N
47	Dupuytrens contrac.	N1	ansell	staph epi +,+	staph epi ++++, ++++	staph epi	staph epi	N	N
47	Dupuytrens contrac.	S2	ansell	clean,clean	staph epi +++,+++	staph epi	staph epi	N	Y

Table 3.4: ***(Sheet 5)*** : The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations). Cases in which both Ansell and Profeel gloves were worn by different team members are shaded yellow. The code letter for the primary surgeon (S1) is given in brackets.

Operation No.	Operation	Team Member	Glove Type	Glove Plates R,L	Hand Swabs Bacteria,R,L	Glove Broth	Hand Broth	Perf R H	Perf L H
49	Exc. lesion hand (R)	S1 (I)	ansell	clean,staph epi +	staph epi +++,++++	staph epi	staph epi	N	N
51	Exc lymph Node Neck	S1 (C)	ansell	staph epi+,+	staph epi++,++	staph epi	staph epi	N	N
51	Exc lymph Node Neck	A1	ansell	clean, staph epi+	staph epi+,++	clean	staph epi	N	N
51	Exc lymph Node Neck	N1	ansell	clean, clean	clean,staph epi +	clean	staph epi	Y	Y
52	Exc Neck lesion back	S1 (C)	ansell	clean,clean	staph epi++,++	clean	staph epi	N	N
52	Exc Neck lesion back	A1	ansell	staph epi+,+	staph epi++,++	staph epi	staph epi	N	N
52	Exc Neck lesion back	N1	ansell	staph epi+,clean	staph epi+,+++	staph epi	staph epi	N	N
54	Skin graft groin - hand	A2	ansell	staph epi+,+	staph ++,++	staph epi	staph epi	N	N
54	Skin graft groin -hand	N1	ansell	contaminated,clean	staph epi +++,++++	staph epi	staph epi	Y	N
55	Breast bx/axillary cl.	S1	ansell	clean,clean	staph epi +++,++++	staph epi	staph epi	N	N
55	Breast bx/axillary cl	A1 (A)	ansell	clean,clean	staph epi ++,++	clean	staph epi	N	N
55	Breast bx/axillary cl	N1	ansell	clean,clean	staph ++++,++++	clean	staph epi	N	N
57	Parathyroidectomy	N1	ansell	clean,clean	staph epi +++,++	staph epi	staph epi	Y	N
58	Cholecystectomy	S1 (B)	ansell	staph epi +,clean	staph epi +,clean	staph epi	staph epi	N	N
58	Cholecystectomy	A1	ansell	clean,clean	staph epi +++,++	clean	staph epi	N	N
59	Breast lump	N1	ansell	clean,clean	staph epi +++,+	staph epi	staph epi	Y	N

Table 3.4: ***(Sheet 6)*** : The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations). Cases in which both Ansell and Profeel gloves were worn by different team members are shaded yellow. The code letter for the primary surgeon (S1) is given in brackets.

Operation No	Operation	Team Member	Glove Type	Glove Plates R,L	Hand Swabs Bacteria,R,L	Glove Broth	Hand Broth	Perf R H	Perf L H
62	Extensor synovectomy	A1	ansell	clean,clean	staph epi ++,++	staph epi	staph epi	N	N
62	Extensor synovectomy	N1	ansell	clean,staph epi +	staph epi +++,+++	staph epi	staph epi	N	Y
62	Extensor synovectomy	A2	ansell	clean,clean	staph epi +++,++++	staph epi	staph epi	N	N
63	Exc ganglion R wrist	N1	ansell	clean,clean	staph epi ++,++	staph epi	staph epi	N	N
64	Ex. lymph node neck	S1 (M)	ansell	clean,clean	staph epi +++,++++	clean	staph epi	N	N
64	Ex. lymph node neck	N1	ansell	clean,clean	staph epi +,+	clean	staph epi	N	N
65	Cholecystectomy	N1	ansell	clean,clean	staph epi ++,++	clean	staph epi	N	N
67	Parathyroid in forearm	N1	ansell	staph epi +,clean	staph epi ++,++	staph epi	staph epi	N	N
69	Ex SCC L hand	S1 (K)	ansell	staph epi +,++/bacilli+	clean,clean	staph epi, aure, bacil	staph epi	N	N
69	Ex SCC L hand	A1	ansell	clean,clean	staph epi +,+	staph aure, bacil	staph epi	N	N
69	Ex SCC L hand	N1	ansell	clean,clean	staph epi +,+++	staph epi	staph epi	N	N
70	Temporal mass	N1	ansell	staph epi +,clean	staph epi +,+	staph epi	staph epi	N	N
71	Mastectomy Ax clear.	N1	ansell	staph epi +,+	staph epi ++,+	staph epi, aure	staph epi	Y	N
74	Ex Axillary Lym Node	S1 (M)	ansell	staph epi +,++	staph epi +,++	staph epi	staph epi	N	N
74	Ex Axillary Lym Node	A1	ansell	staph epi +,+	clean,staph epi +	staph epi & bacil	staph epi	N	N
74	Ex Axillary Lym Node	N1	ansell	staph epi+,clean	staph epi ++,+++	staph epi & bacil	staph epi & aure	N	N
75	Ing. Hernia	N1	ansell	clean,staph epi +	staph +++,+ & bacil	staph epi	staph epi & bacil	N	N
76	Thyroidectomy	S1 (M)	ansell	clean,staph epi +	staph epi +++,+++	staph epi	staph epi	N	N
76	Thyroidectomy	A1	ansell	clean,clean	staph epi ++,++	staph epi	staph epi	N	N
76	Thyroidectomy	A2	ansell	clean,clean	staph epi ++,+	staph aur	staph epi	N	N
78	Cholecystectomy	S1 (C)	ansell	clean,clean	staph epi +,+	staph epi	staph epi	N	N
78	Cholecystectomy	A1	ansell	clean,clean	clean,clean	clean	clean	N	N
78	Cholecystectomy	N1	ansell	clean,clean	staph epi ++,+++	clean	staph epi	N	N

Table 3.4: *(Sheet 7)* : The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations). Cases in which both Ansell and Profeel gloves were worn by different team members are shaded yellow. The code letter for the primary surgeon (S1) is given in brackets.

Operation No	Operation	Team Member	Glove Type	Glove Plates R,L	Hand Swabs Bacteria R,L	Glove Broth	Hand Broth	Perf R H	Perf L H
80	Ing. Hernia	N1	ansell	clean,clean	staph epi +++,+++	staph epi	staph epi	N	N
82	Breast Lump	N1	ansell	clean,clean	staph epi +,+	staph epi	staph epi	N	N
84	Ing. Hernia	S1 (M)	ansell	staph epi +,++	staph epi +++,+++	staph epi & bacil	staph epi	N	N
85	Exc Lesion Back. Hand	N1	ansell	clean,clean	staph epi ++,++	clean	staph epi	N	N
88	Wire loc. Breast Bx	N1	ansell	clean,clean	staph epi ++,++	clean	staph epi	N	N
91	Thyroidectomy	N1	ansell	clean,clean	staph epi +++,++	staph epi	staph epi	N	N
92	Breast Lump	S1 (C)	ansell	clean,clean	staph epi +++,++	clean	staph epi &bacil	N	N
92	Breast Lump	N1	ansell	clean,clean	staph aura ++,+	clean	staph aura	N	N
93	Palmar fasciectomy	A1	ansell	staph epi +,+	staph epi +++,+++	staph epi	staph epi	N	N
93	Palmar fasciectomy	N1	ansell	clean,clean	staph epi +++,+++	staph epi	staph epi &bacil	N	N
96	Vasectomy	S1 (K)	ansell	staph epi +++,+++	staph epi ++,++	staph epi	staph epi	N	N
96	Vasectomy	N1	ansell	staph epi +,+	staph epi +++,++++	-	staph epi &bacil	Y	N
98	Ing. Hernia	S1 (K)	ansell	staph epi +++,+++	staph epi ++,++	staph epi	staph epi	N	N
98	Ing. Hernia	A1	ansell	staph epi +++,++	clean,clean	staph epi	staph epi &bacil	N	N
98	Ing. Hernia	N1	ansell	staph epi ++,+	staph epi ++++,++++ & bacil ++++	staph epi	staph epi &bacil	N	N

Table 3.4: *(Sheet 8)* : The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations). Cases in which both Ansell and Profeel gloves were worn by different team members are shaded yellow. The code letter for the primary surgeon (S1) is given in brackets.

Operation No	Operation	Team Member	Glove Type	Glove Plates R,L	Hand Swabs Bacteria,R,L	Glove Broth	Hand Broth	Perf R H	Perf L H
13	Breast lump	S1 (A)	profeel	clean,staph epi ++	staph epi ++,+++	staph epi	staph epi	N	N
13	Breast lump	A1	profeel	staph epi ++,++	staph epi +,++	staph epi	staph epi	N	N
13	Breast lump	N1	profeel	clean,clean	staph epi +++,+++	staph epi	staph epi	N	N
15	Thyroidectomy	S1 (A)	profeel	clean,clean	staph epi ++,+++	staph epi	staph epi	N	N
15	Thyroidectomy	A1	profeel	clean,clean	staph epi +,+	staph epi	staph epi	N	N
15	Thyroidectomy	N1	profeel	clean,clean	staph epi +++,++	staph epi	staph epi	Y	Y
15	Thyroidectomy	A2	profeel	clean,clean	clean,clean	clean	clean	N	N
16	Breast biopsy	S1 (E)	profeel	staph epi ++,++	staph epi ++,+++	staph epi	staph epi	N	N
16	Breast biopsy	A1	profeel	staph epi ++,++	staph epi +,+	staph epi	staph epi	N	N
16	Breast biopsy	N1	profeel	staph epi +,+	staph epi ++,++	staph epi	staph epi	N	N
19	High lig. (L) vv's	S1 (D)	profeel	clean,clean	staph epi +++,+++	clean	stap epi	N	N
19	High lig. (L) vv's	A1	profeel	staph epi +,clean	clean,clean	stap epi	stap epi	N	N
19	High lig. (L) vv's	N1	profeel	staph epi +,clean	staph epi ++,+++	stap epi	stap epi	N	N
22	Exc. bx (R) breast	S1 (A)	profeel	staph aure+,++	staph epi ++,+++	staph aure & epi	staph epi	N	N
22	Exc. bx (R) breast	A1	profeel	clean,staph aure++	staph epi +++,++	staph aure	staph epi	N	N
22	Exc. bx (R) breast	N1	profeel	clean,clean	staph epi +++,+++	staph aure	staph epi	N	N
23	Exc. branchial cyst (R) side neck	S1 (A)	profeel	staph epi ++,+ & aure	staph epi ++,+++	staph epi & aure	staph epi	N	N
23	Exc. branchial cyst (R) side neck	A1	profeel	staph epi++,++ & aure	staph epi ++,+++	staph epi & aure	staph epi	N	Y
23	Exc. branchial cyst (R) side neck	N1	profeel	clean,staph epi +	staph epi ++,+++	staph epi	staph epi	N	N

Table 3.4: ***(Sheet 9)*** : The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations). Cases in which both Ansell and Profeel gloves were worn by different team members are shaded yellow. The code letter for the primary surgeon (S1) is given in brackets.

Operation No	Operation	Team Member	Glove Type	Glove Plates R,L	Hand Swabs Bacteria,R,L	Glove Broth	Hand Broth	Perf R H	Perf L H
25	Ing. hernia	S1 (A)	profeel	staph epi ++,+	staph epi +++,+++ & aure	staph epi	staph epi & aure	N	N
25	Ing. hernia	A1	profeel	staph epi +,+	staph epi ++,++	clean	staph epi	N	N
25	Ing. hernia	N1	profeel	staph epi ++,+	staph epi +++,+++	staph epi	stpah epi & aure	N	N
26	Thyroidectomy	S1 (A)	profeel	staph epi ++,++	staph epi ++,+++	staph epi	staph epi	N	N
26	Thyroidectomy	A1	profeel	staph epi ++,++	staph epi ++,++	staph epi	staph epi	N	N
26	Thyroidectomy	N1	profeel	clean,clean	staph epi ++++,++++	clean	staph epi	N	N
26	Thyroidectomy	A2	profeel	staph epi+,+	staphepi++,+++	staph epi	staph epi	N	N
27	Varicocele	S1 (B)	profeel	staph epi ++,+	clean,clean	staph epi	staph epi	N	N
27	Varicocele	A1	profeel	clean,staph epi +	staph epi +++,+++	staph epi	staph epi	N	N
27	Varicocele	N1	profeel	clean,clean	staph epi +++,+++	staph epi	staph epi	N	N
30	Ing. hernia	S1 (G)	profeel	clean,clean	staph epi +++,+++	staph epi	staph epi	Y	N
30	Ing. hernia	A1	profeel	staph epi +,clean	staph epi +++,+++	clean	staph epi	N	N
30	Ing. hernia	N1	profeel	staph epi +,+	staph epi +++,+++	staph epi	staph epi	N	N
34	Elev Zygoma	S1 (I)	profeel	staph epi +++, +++	staph epi++++,++++	staph epi	staph epi & bacil	N	N
34	Elev Zygoma	A1	profeel	staph epi +++, +++	clean,staph epi +	staph epi & aure	staph epi	N	N
34	Elev Zygoma	N1	profeel	staph epi ++, +++	staph epi +++,++++	staph epi	staph epi	N	N
36	Thyroidectomy	S1 (A)	profeel	clean,clean	staph epi ++,+++	staph epi & aure	staph epi	N	N
36	Thyroidectomy	A1	profeel	clean,clean	staph epi ++,+	staph epi & aure	staph epi	N	N
36	Thyroidectomy	N1	profeel	staph epi +,clean	staph epi ++,+++	staph epi, aure & bacilli	staph epi	N	N
36	Thyroidectomy	S2	profeel	staph epi +,+ aure+	staph epi ++,++	staph epi & aure	staph epi	N	N

Table 3.4: ***(Sheet 10)*** : The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations). Cases in which both Ansell and Profeel gloves were worn by different team members are shaded yellow. The code letter for the primary surgeon (S1) is given in brackets.

Operation No	Operation	Team Member	Glove Type	Glove Plates R,L	Hand Swabs Bacteria R,L	Glove Broth	Hand Broth	Perf R H	Perf L H
39	Resec. BCC ear	S1 (I)	profeel	staph epi +++,+++ & aure+++,+++	staph epi +++,++	staph epi & aure	staph epi	N	N
39	Resec. BCC ear	A1	profeel	staph epi ++,++ & aure+,+	clean,clean	staph epi & aure	staph epi	N	N
39	Resec. BCC ear	N1	profeel	staph epi +,+ & aure+,clean	staph epi +,++	staph epi & aure	staph epi	N	N
39	Resec. BCC ear	N2	profeel	staph epi +,+ & aure+,+	staph epi ++++,++++	staph aure	staph epi	N	N
41	Exc. lesion (R) ear	S1 (I)	profeel	staph epi +++,+++	staph epi ++++,++++	staph epi & aure	staph epi	N	N
41	Exc. lesion (R) ear	A1	profeel	staph epi +++,contaminated	staph epi +,++	staph epi & aure	staph epi	N	N
41	Exc. lesion (R) ear	N1	profeel	staph epi +,+	staph epi ++++,++++	staph epi & aure	staph epi	N	N
41	Exc. lesion (R) ear	N2	profeel	staph epi +++,+	staph epi ++,+++	staph epi & aure	staph epi	N	N
44	Stab avulsions (R) leg	S1 (K)	profeel	clean,clean	clean,clean	clean	staph epi	N	N
44	Stab avulsions (R) leg	N1	profeel	clean,clean	clean,clean	staph epi	staph epi	N	N
48	Exc. Ganglion wrist	S1 (H)	profeel	clean,contaminated	staph epi +++,+++	clean	staph epi	N	N
48	Exc. Ganglion wrist	A1	profeel	clean,clean	staph epi +,clean	clean	staph epi & aure	N	N
48	Exc. Ganglion wrist	N1	profeel	clean,clean	staph epi ++,++	staph aure	staph epi	N	N
49	Exc. lesion hand (R)	A1	profeel	staph epi +,clean	staph epi ++,clean	staph epi	staph epi	N	N
49	Exc. lesion hand (R)	N1	profeel	clean,clean	staph epi +,++	clean	staph epi	N	N

Table 3.4: ***(Sheet 11)*** : The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations). Cases in which both Ansell and Profeel gloves were worn by different team members are shaded yellow. The code letter for the primary surgeon (S1) is given in brackets.

Operation No	Operation	Team Member	Glove Type	Glove Plates R,L	Hand Swabs Bacteria,R,L	Glove Broth	Hand Broth	Perf R H	Perf L H
53	Breast lump	A1	profeel	staph epi+,+	staph epi +,+	staph epi , baci	staph epi	N	N
53	Breast lump	A2	profeel	clean,staph epi++	staph epi +++,+++	staph epi	staph epi	N	N
53	Breast lump	N1	profeel	clean,staph epi +	staph epi ++,+++	staph epi	staph epi, baci	N	N
56	Thyroidectomy	S1 (A)	profeel	clean,clean	staph epi ++ baci ++,+++	clean	staph epi, aure, baci	N	N
56	Thyroidectomy	A1	profeel	staph epi +,clean	clean,staph epi +& baci +,+	staph epi	staph epi	N	N
56	Thyroidectomy	A2	profeel	staph epi +,+	staph epi ++,+++	staph epi	staph epi	N	N
56	Thyroidectomy	N1	profeel	clean,clean	staph epi +++,+++	staph epi	staph epi, baci	N	Y
57	Parathyroidectomy	S1 (C)	profeel	clean,clean	staph epi +++,+++	staph epi	staph epi	N	N
57	Parathyroidectomy	A1	profeel	clean,clean	staph epi ++,+++	staph epi	staph epi	N	N
57	Parathyroidectomy	S2	profeel	clean,clean	staph epi +++,+++	clean	staph epi	N	N
59	Breast lump	S1 (L)	profeel	staph epi ++,++	clean,clean	staph epi	staph epi	N	Y
59	Breast lump	A1	profeel	staph epi ++,++	clean,clean	staph epi	staph epi	N	N
60	Ing. Hernia	S1 (L)	profeel	staph epi +++,+++	clean,staph epi +	staph epi	staph epi	N	N
60	Ing. Hernia	A1	profeel	staph epi +,++	staph epi +,+	staph epi	staph epi	N	N
60	Ing. Hernia	N1	profeel	clean,clean	staph epi +,++	clean	staph epi	N	N
61	Needle local & breast biopsy	S1 (B)	profeel	clean,staph epi +	staph epi ++,+++	staph epi	staph epi	N	N
61	Needle local & breast biopsy	A1	profeel	clean,clean	clean,staph epi+	staph epi	staph epi	N	N

Table 3.4: ***(Sheet 12)*** : The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations). Cases in which both Ansell and Profeel gloves were worn by different team members are shaded yellow. The code letter for the primary surgeon (S1) is given in brackets.

Operation No	Operation	Team Member	Glove Type	Glove Plates R,L	Hand Swabs Bacteria,R,L	Glove Broth	Hand Broth	Perf R H	Perf L H
63	Exc ganglion wrist	S1 (H)	profeel	clean,clean	staph epi +++,++	staph epi	staph epi	N	N
63	Exc ganglion wrist	A1	profeel	staph epi +,clean	staph epi +++,++	staph epi	staph epi	N	N
65	Cholecystectomy	S1 (C)	profeel	clean,clean	staph epi +++,+++	clean	staph epi	N	N
65	Cholecystectomy	A1	profeel	clean,clean	staph epi +++,++++	staph epi	staph epi	N	N
65	Cholecystectomy	A2	profeel	clean,clean	staph epi +,++	clean	staph epi	N	N
66	Breast lump	S1 (C)	profeel	clean,clean	staph epi +++,+++	baci	staph epi	N	N
66	Breast lump	A1	profeel	clean,clean	staph epi +++,+++	staph epi	staph epi	N	N
66	Breast lump	S2	profeel	clean,clean	staph epi +,+	staph epi	staph epi	N	N
67	Parathyroid in forearm	S1 (C)	profeel	clean,clean	staph epi ++,+++	clean	staph epi	N	N
67	Parathyroid in forearm	A1	profeel	clean,clean	staph epi ++,+++	baci	staph epi	N	N
68	Axillary Dissection	S1 (B)	profeel	staph epi ++,++	staph epi +,+	staph epi	staph epi	N	N
68	Axillary Dissection	A1	profeel	staph epi +++,+++	staph epi +++,+++	staph epi	staph epi	N	N
68	Axillary Dissection	N1	profeel	staph epi ++,+	staph epi +++,+++	staph epi	staph epi	Y	N
70	Temporal mass	S1 (K)	profeel	staph epi +,++	staph epi +,+	staph epi, baci	staph epi	N	N
70	Temporal mass	A1	profeel	clean,clean	clean,clean	staph epi	staph epi	N	N
71	Mastectomy Ax clear	A1	profeel	staph epi +,clean	clean,staph epi +	staph epi, aure	staph epi	N	N
71	Mastectomy Ax clear	A2	profeel	staph epi +,++	staph epi +,clean	staph epi, aure	staph epi, baci	N	N

Table 3.4: ***(Sheet 13)*** : The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations). Cases in which both Ansell and Profeel gloves were worn by different team members are shaded yellow. The code letter for the primary surgeon (S1) is given in brackets.

Operation No	Operation	Team Member	Glove Type	Glove Plates R,L	Hand Swabs Bacteria,R,L	Glove Broth	Hand Broth	Perf R H	Perf L H
72	Ulnar Nerve Release	S1 (N)	profeel	clean,clean	staph epi +,+	staph epi	staph epi	N	N
72	Ulnar Nerve Release	A1	profeel	clean,clean	staph epi +,+	clean	staph epi	N	N
72	Ulnar Nerve Release	N1	profeel	clean,clean	staph epi +++,+++	staph epi	staph epi	N	N
73	SCC face & Ex. lesion	S1 (N)	profeel	staph epi ++,+++	staph epi +++,+++	staph aure	staph epi	N	N
73	SCC face & Ex. lesion	N1	profeel	staph epi +,++	staph epi ++++,++++	staph epi, aure	staph epi	N	N
75	Ing. Hernia	S1 (K)	profeel	staph epi +,++	staph epi ++++,++++	staph epi	staph epi	N	N
75	Ing. Hernia	A1	profeel	staph epi +,+	staph epi +,+	staph epi	staph epi	N	N
77	Bil Varicose Veins	S1 (M)	profeel	clean,staph epi + & bacil	staph epi +,+	staph epi	staph epi & aur	N	N
77	Bil Varicose Veins	N1	profeel	staph epi +,clean& bacil	staph epi ++++,++++	staph epi	staph epi & bacil	N	N
79	Breast Lump	S1 (M)	profeel	clean,clean	staph epi +++,+++	staph epi	staph epi	N	N
79	Breast Lump	A1	profeel	clean,clean	staph epi +,clean	staph epi	staph epi	N	N
79	Breast Lump	N1	profeel	clean,clean	staph epi +,+	clean	staph epi	N	N
80	Ing. Hernia	S1 (B)	profeel	clean,clean	clean,staph epi+	staph epi & bacil	staph epi	N	N
80	Ing. Hernia	A1	profeel	clean,clean	staph epi +++,+++	staph epi	staph epi	N	N
81	Ing. Hernia	S1 (B)	profeel	clean,staph epi+	clean,clean	staph epi	staph epi	N	N
81	Ing. Hernia	A1	profeel	clean,staph epi+	staph epi +,clean	staph epi	clean	N	N
81	Ing. Hernia	N1	profeel	clean,staph epi+	staph epi +++,+++	staph epi	staph epi & bacil	N	N

Table 3.4: ***(Sheet 14)*** : The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations). Cases in which both Ansell and Profeel gloves were worn by different team members are shaded yellow. The code letter for the primary surgeon (S1) is given in brackets.

Operation No	Operation	Team Member	Glove Type	Glove Plates R,L	Hand Swabs Bacteria,R,L	Glove Broth	Hand Broth	Perf R H	Perf L H
82	Breast Lump	S1 (K)	profeel	clean,staph epi+	staph epi +,++	staph epi	staph epi	N	N
82	Breast Lump	A1	profeel	clean,staph epi+	staph ++,+++	staph epi	staph epi	N	N
83	Subareolar breast exc	S1 (L)	profeel	staph epi +,+	clean,clean	staph epi	staph epi	N	N
83	Subareolar breast exc	A1	profeel	clean,clean	staph epi +,++	clean	staph epi	N	N
83	Subareolar breast exc	N1	profeel	clean,clean	staph epi ++,clean	staph epi	staph epi	N	N
84	Ing. Hernia	A1	profeel	staph epi +,+	staph epi +,clean	staph epi	staph epi	N	N
84	Ing. Hernia	N1	profeel	staph epi +,clean& bacil	staph ++,+++	staph epi	staph epi	N	Y
85	Exc Lesion R. Hand	S1 (C)	profeel	clean,clean	staph epi +++,+++	clean	staph epi	N	N
85	Exc Lesion R. Hand	A1	profeel	staph epi +,+	staph epi +,+	clean	staph epi	N	N
86	Elevation # zygoma	S1 (L)	profeel	staph epi ++,+++	staph epi ++,++	staph epi	staph epi	N	N
86	Elevation # zygoma	A1	profeel	staph epi +++,+	staph epi +++,+++	staph epi , aura & bacil	staph epi	N	N
86	Elevation # zygoma	N1	profeel	staph epi +,+	staph epi ++++,+++	staph epi & aura	staph epi	N	N
87	Elevation # zygoma	S1 (L)	profeel	staph epi +,++ &bacill	staph epi +,+	staph epi	staph epi	N	N
87	Elevation # zygoma	A1	profeel	staph epi +,++ & bacill	staph epi ++++,++++	staph epi , aura & bacil	staph epi	N	N
87	Elevation # zygoma	N1	profeel	clean,clean	staph epi ++++,++++	staph epi & aura	staph epi	N	N
88	Needle loc breast bx.	S1 (L)	profeel	staph epi +++,++	staph epi +,+	staph epi & bacil	staph epi	N	N
88	Needle loc breast bx.	A1	profeel	clean,staph epi +	staph epi ++,+++	staph epi	staph epi	N	N

Table 3.4: *(Sheet 15)* : The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations). Cases in which both Ansell and Profeel gloves were worn by different team members are shaded yellow. The code letter for the primary surgeon (S1) is given in brackets.

Operation No	Operation	Team Member	Glove Type	Glove Plates R,L	Hand Swabs Bacteria,R,L	Glove Broth	Hand Broth	Perf R H	Perf L H
89	Breast bx	S1 (M)	profeel	clean,clean	staph epi +++,+++	staph epi	staph epi	N	N
89	Breast bx	A1	profeel	clean,staph epi +	staph epi +,clean	staph epi	staph epi	N	N
89	Breast bx	N1	profeel	clean,clean	staph epi ++++,+++	staph epi	staph epi & bacil	N	N
90	Axillary clearance	S1 (A)	profeel	staph epi +,+	staph epi ++++,++++	staph epi	staph epi	N	N
91	Thyroidectomy	S1 (A)	profeel	clean,clean	staph epi ++++,++++	clean	staph epi & aura	N	N
91	Thyroidectomy	A1	profeel	clean,clean	clean,clean	clean	staph epi	N	N
94	Breast bx	S1 (L)	profeel	clean,clean	clean,staph epi +	staph epi & bacil	staph epi	N	N
94	Breast bx	A1	profeel	clean,clean	clean,staph epi +	staph epi & bacil	staph epi	N	N
94	Breast bx	N1	profeel	clean,clean	staph epi +++,+++	staph epi	staph epi	N	N
95	Breast bx	S1 (K)	profeel	clean,staph epi +	staph epi +,+	staph epi	staph epi	N	N
95	Breast bx	A1	profeel	staph epi +,clean	staph epi +++,+++	staph epi	staph epi	N	N
95	Breast bx	N1	profeel	clean,clean	staph epi +,++	staph epi	staph epi	N	N
97	Ing Hernia	S1 (B)	profeel	staph epi ++,+++	clean,clean	staph epi	staph epi & bacil	N	N
97	Ing Hernia	A1	profeel	staph epi ++,++	staph epi +,++	staph epi	staph epi	N	N
97	Ing Hernia	N1	profeel	staph epi +, contam	staph epi +++,+++	staph epi	staph epi	N	N
99	Ing Hernia	S1 (K)	profeel	staph epi +++,+++	staph epi ++++,+++	staph epi	staph epi	N	N
99	Ing Hernia	A1	profeel	staph epi +,+	staph epi +,clean	staph epi	staph epi	N	N
99	Ing Hernia	N1	profeel	staph epi +,+	staph epi +++,+++	staph epi & bacil	staph epi	N	N

Table 3.4: ***(Sheet 16)*** : The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations). Cases in which both Ansell and Profeel gloves were worn by different team members are shaded yellow. The code letter for the primary surgeon (S1) is given in brackets.

3.2.3 Perforation Rates for Each Scrub-Team Member

Table 3.5 shows the number of each type of individual involved in the scrub team and the number and percentage of those individuals who sustained one or more perforations (there were only two individuals who perforated both of their gloves - one *Nurse 1* wearing Profeel, and one *Nurse 1* wearing Ansell)[1]

[1] hence 28 individuals with perforations - but 30 gloves with perforations.

Scrub Team Member	Ansell No. individuals (Perforated)	%	Profeel No.individuals (Perforated)	%	Total No.individuals (Perforated)	%
S_1	43(2)	4.8	47(2)	4.2	90(4)	4.4
S_2	9(2)	22.2	4(0)	0	13(2)	15.4
A_1	38(4)	10.5	47(1)	2.1	55(5)	9.1
A_2	6(2)	33.3	6(0)	0	12(2)	16.7
N_1	54(11)	20.4	35(4)	11.4	89(17)	19.1
N_2	2(0)	0	2(0)	0	4(0)	0
Total	152(21)	13.8	141(7)	5.0	293(28)	9.6

Table 3.5: Number of each type of individual involved in the scrub team and the number and percentage of those individuals who sustained one or more perforations (two individuals sustained perforations of both their gloves - see text).

3.2.4 Perforation Rates for Left and Right Hands

From Table 3.3 it can be seen that there were 30 glove perforations in 28 individuals (two individuals perforated both gloves). Sixteen perforations occurred in the left glove, and fourteen in the right glove.

3.2.4 Perforation Rates for Primary Surgeons

The perforation rates for each individual primary surgeon are shown in the raw data in Table 3.3, and are summarised in Table 3.6.

Surgeon Code	Ansell (Perforated)	Profeel (Perforated)	Operations during which perforation occurred	Total Operations	Total Perforated (%)
A	12 (0)	10 (0)	-	22	0 (0)
B	3 (1)	6 (0)	laparoscopy	9	1 (11)
C	6 (0)	5 (0)	-	11	0 (0)
D	3 (1)	1 (0)	varicose vein	4	1 (25)
E	1 (0)	1 (0)	-	2	0 (0)
F	2 (0)	0 (0)	-	2	0 (0)
G	3 (0)	1 (1)	ing hernia	4	1 (25)
H	3 (0)	2 (0)	-	5	0 (0)
I	2 (0)	3 (0)	-	5	0 (0)
J	1 (0)	0 (0)	-	1	0 (0)
K	3 (0)	6 (0)	-	9	0 (0)
L	0 (0)	7 (1)	breast biopsy	7	1 (14)
M	4 (0)	3 (0)	-	7	0 (0)
N	0 (0)	2 (0)	-	2	0 (0)
Total	**43 (2)**	**47 (2)**		**90**	**4.4%**

Table 3.6: Operation and glove perforation details for primary surgeons.

3.3 Microbial Culture Analysis of Gloves and Hands and Wound Infections

The raw data for all gloves with regard to microbial culture of gloves and hands (as well as perforations) is given in Table 3.3. The majority of all personnel in the scrub team grew bacteria consistent with the normal skin flora of the wearer. All operations in this study were classified as clean or clean-contaminated. Follow-up of all patients showed no wound

infection in any patient. This was consistent with the independent Wound Survey run by the Infection Control Department of the Royal Hobart Hospital which consistently reports a "clean wound" infection rate for the Hospital of <0.5%.

4.0 DISCUSSION

4.1 Baseline Perforation Rate of Unused Gloves

By Chi squared analysis, the difference in perforation rates of unused samples of the two brands of gloves (1/110 Profeel batch tested; 0/110 Ansell individually tested) was not statistically significant. It could be argued that since individually tested gloves are all tested and guaranteed to be supplied without any perforation, that even one perforation in a batch-tested glove is potentially clinically significant. Such clinical significance could be manifest as an increased wound infection rate (transmission from operating team to patient), or an increased risk of transmission of blood-borne pathogens (eg. hepatitis B or C, or HIV) from the patient to the operating team. The latter incidence is known to be extremely low, and was not tested in this study. No argument could be reasonably raised however, against using individually tested gloves as part of universal precautions in known carriers of such pathogens. Some surgeons utilize double-gloving (with one pair of gloves half-size larger than their standard hand size either inside or outside of the normal size glove) part of universal

precautions in all cases. This technique reduces macroscopic perforations to extremely low levels (see Literature Review), so that there could be expected to be no significant difference in perforation rates between the two brands of gloves under such circumstances.

Transmission of bacterial pathogens from operating team to patient was tested in this study, by comparing wound infection rates for procedures carried out using either type of glove, and relating this to the bacteriologic studies of the hands of the scrub team. These results produced unexpected findings and are discussed in detail in Section 4.3. It appears that for the types of operations examined in this study, the baseline perforation rate of unused gloves was of no significance to the patient in terms of wound infection rates.

4.2 Glove Perforation Rates Following Surgery

Table 3.1 showed that the perforation rates following surgery were 22/304 for Ansell gloves and 8/282 for Profeel gloves. Chi squared analysis was set out in Tables 3.2 and 3.3,

indicating that this difference was statistically significant ($p<0.05$). The reasons for this difference between brands could potentially be due to differences in glove quality (eg. strength of materials), or differences in the uses to which the gloves were put (eg. types of procedures; use of more of one brand by team members more likely to sustain a perforation; deliberate rough handling of gloves of a particular brand [non-blind bias]).

The only measure of quality of materials carried out in this study was the base-line perforation rate of unused gloves. Latex qualities (eg. elasticity, thickness, tensile strength) were not examined. We assumed that because these gloves conformed to Australian standards, there were not significant differences in latex properties (note however that indirect evidence of a difference in latex properties was uncoverered in the bacteriologic analysis, discussed in Section 4.3).

Regarding types of procedures to which each glove type were subjected, these are set out in detail in Table 3.4 and summarized in Table 2.1. It is apparent that Ansell gloves were used more often for minor general surgical procedures (24 Ansell vs. 12 Profeel) and thyroidectomy and parathyroidectomy (13 Ansell vs. 6 Profeel). Profeel were used more often for breast biopsies (14 Profeel vs. 6 Ansell). It

is possible that this discrepancy could account for the higher Ansell perforation rate if it could be shown that more perforations occurred for minor operations and/or thyroid/parathyroid operations, and/or less perforations occurred for breast biopsy procedures. The rate of glove perforation for each operation is shown below in Table 4.1.

			Ansell	Profeel
A.	Thyroidectomy/ parathyroidectomy	perforation	7	3
		no perforation	67	39
			(13)	*(6)*
B.	Minor Surgical	perforation	7	1
		no perforation	107	61
			(24)	*(12)*
C.	Breast Biopsy	perforation	1	1
		no perforation	17	75
			(6)	*(14)*

Table 4.1: No. gloves used for thyroidectomy/parathyroidectomy, breast biopsy, and minor surgical procedures (number of operations italics in brackets).

These can be analyzed as operations in which significantly more Ansell gloves were worn (groups A and B, 37 Ansell vs. 18 Profeel), and operations in which significantly more Profeel

gloves were worn (group C, 6 Ansell vs. 14 Profeel). Chi-squared analysis is set out below.

Glove Type	Perforation	No Perforation	Total
Ansell	14	174	188
Profeel	4	100	104
Total	18	274	292

Table 4.2: Observed numbers of glove perforations for Ansell and Profeel gloves in groups A and B (thyroidectomy/parathyroidectomy + minor surgical procedures).

Glove Type	Perforation	No Perforation	Total
Ansell	188/292*18 = 11.589	183/292*274 = 176.411	188
Profeel	104/292*18 = 6.411	104/292*274 = 97.589	104
Total	18	274	292

Table 4.3: Calculation of expected numbers of perforations for Ansell and Profeel gloves in groups A+B, assuming the Null hypothesis that there is no significant difference in perforation rates between the two glove types in groups A+B.

Glove Type	Perforation	No. Perforation
Ansell	14 - 11.589 = 2.411	174 - 176.411 = -2.411
Profeel	4 - 6.411 = -2.411	100 - 97.589 = 2.411

Table 4.4: Observed - expected calculations for chi-squared statistic with one degree of freedom ($\chi^2_{(1)}$) for groups A+B operations.

$$\chi^2_{(1)} = \Sigma (O - E)^2 / E$$

$$= (2.411)^2/11.589 + (-2.411)^2/176.411 + (-2.411)^2/6.411 + (2.411)^2/97.589$$

$$= 1.501$$

$p > 0.1$. Therefore the null hypothesis is accepted, that there is no statistically significant difference between the perforation rates for each glove type for group A and B operations.

$\chi^2_{(1)}$ analysis for group C operations (breast biospy) is set out below in Tables 4.5, 4.6 and 4.7.

Glove Type	Perforation	No Perforation	Total
Ansell	1	11	12
Profeel	1	46	47
Total	2	57	59

Table 4.5: Observed numbers of glove perforations for Ansell and Profeel gloves in group C (breast biopsy).

Glove Type	Perforation	No Perforation	Total
Ansell	12/59*2 = 0.407	12/59*57 = 11.593	12
Profeel	47/59*2 = 1.593	47/59*57 = 45.407	47
Total	2	57	59

Table 4.6: Calculation of expected numbers of perforations for Ansell and Profeel gloves in group C, assuming the null hypothesis that there is no significant difference in perforation rates between the two glove types in group C.

Glove Type	Perforation	No Perforation
Ansell	1 - 0.407 = 0.593	11 - 11.593 = -0.593
Profeel	1 - 1.593 = -0.593	46 - 45.407 = 0.593

Table 4.7: Observed - expected calculations for chi-squared statistic with one degree of freedom ($\mathcal{X}^2_{(1)}$) for group C operations.

$$\chi^2_{(1)} = \sum (O - E)^2 / E$$

$$= (0.593)^2/0.407 + (-0.593)^2/11.593 + (-0.593)^2/1.593 + (0.593)^2/45.407$$

$$= 1.123$$

$p > 0.1$. Therefore the null hypothesis is accepted, that there is no statistically significant difference between the perforation rates for each glove type for group C operations (breast biopsies).

Regarding potential bias of type of operator as a cause for the overall difference in perforation rate between Ansell and Profeel gloves, it could be that if significantly more of a particular type of scrub team member wore more of a particular glove brand, then an explanatory bias would be present separate from the glove brand. Table 3.5 summarizes the numbers and types of each scrub team member wearing each brand of glove. For first surgeon, there were similar numbers of gloves used (43 Ansell vs. 47 Profeel), and similar numbers of perforations for each (2 and 2 respectively).

For second surgeon there were 2 perforations out of 9 Ansell gloves, and zero perforations out of 4 Profeel gloves. These numbers are too small for statistical significance. Similarly, for second assistants, the 2/6 perforation rate for Ansell vs. 0/6 perforation rate for Profeel indicates numbers too small for statistical significance.

There was no difference for second nurses. However there are potentially significant differences for first assistant (4 perforations/38 gloves for Ansell vs. 1 perforation out of 47 Profeel gloves). Similarly there is a potentially significant difference for first nurses (11 perforations/54 Ansell gloves vs. 4 perforations/35 Profeel gloves).

For first assistants, the $\chi^2_{(1)}$ statistic is set out in Tables 4.8, 4.9 and 4.10.

Glove Type	Perforation	No Perforation	Total
Ansell	4	34	38
Profeel	1	46	47
Total	5	80	85

Table 4.8: Observed numbers of glove perforations for Ansell and Profeel gloves in the group: first assistants.

Glove Type	Perforation	No Perforation	Total
Ansell	38/85*5 = 2.235	38/85*80 = 35.765	38
Profeel	47/85*5 = 2.765	47/85*80 = 44.235	47
Total	5	80	85

Table 4.9: Calculation of expected numbers of perforations for Ansell and Profeel gloves in the group: first assistants, assuming the null hypothesis that there is no significant difference in perforation rates between the two glove types for first assistants.

Glove Type	Perforation	No Perforation
Ansell	4 - 2.235 = 1.765	34 - 35.765 = -1.765
Profeel	1 - 2.765 = -1.765	46 - 44.235 = 1.765

Table 4.10: Observed - expected calculations for chi-squared statistic with one degree of freedom ($\chi^2_{(1)}$) for the group: first assistants.

$$\chi^2_{(1)} = \Sigma (O - E)^2 / E$$

$$= (1.765)^2/2.235 + (-1.765)^2/35.765 + (-1.765)^2/2.765 + (1.765)^2/44.235$$

$$= 2.678$$

$p > 0.05$. Therefore the null hypothesis is accepted, ie. there is no statistically significant difference between the perforation rates for each glove type for operations by first assistants.

For first nurses, the $\chi^2_{(1)}$ statistic is set out in Tables 4.11, 4.12 and 4.13.

Glove Type	Perforation	No Perforation	Total
Ansell	11	43	54
Profeel	4	31	35
Total	15	74	89

Table 4.11: Observed numbers of glove perforations for Ansell and Profeel gloves in the group: first nurses.

Glove Type	Perforation	No Perforation	Total
Ansell	54/89*15 = 9.101	54/89*74 = 44.899	54
Profeel	35/89*15 = 5.899	35/89*74 = 29.101	35
Total	15	74	89

Table 4.12: Calculation of expected numbers of perforations for Ansell and Profeel gloves in the group: first nurses, assuming the null hypothesis that there is no significant difference in perforation rates between the two glove types in the group: first nurses.

Glove Type	Perforation	No Perforation
Ansell	11 - 9.101 = 1.899	43 - 44.899 = -1.899
Profeel	4 - 5.899 = -1.899	31 - 29.101 = 1.899

Table 4.13: Observed - expected calculations for chi-squared statistic with one degree of freedom ($\chi^2_{(1)}$) for the group: first nurses.

$$\chi^2_{(1)} = \sum (O - E)^2 / E$$

$$= (1.899)^2/9.101 + (-1.899)^2/44.899 + (-1.899)^2/5.899 + (1.899)^2/29.101$$

$$= 1.211$$

$p > 0.1$. Therefore the null hypothesis is accepted, that there is no statistically significant difference between the perforation rates for each glove type for the group: first nurses. There is therefore no evidence for bias in the types of wearers of each glove brand or the types of operations for which each glove brand was used, to account for the significant overall difference in perforation rates for the two glove types.

In summary, overall there was a difference in glove perforation rates between Ansell and Profeel gloves, significant at the 5% level, and this could not be shown by analysis of subgroups to be due to bias in types of glove wearers or types of operations carried out. Neither could bias be inferred from use of more of a particular glove brand by any individual surgeon (Table 3.6). Whilst this data could be interpreted as suggesting that Profeel gloves were less prone to perforation

during these types of surgical procedures, from the perspective of this thesis, the more important interpretation is that there is no disadvantage to use of the batch-tested glove brand, when perforation rates are measured at the end of surgical procedures.

4.3 Significance of Perforations on Clinical Outcome (Wound Infection)

One of the most interesting findings of the bacteriologic data was analysis of the bacterial profile of the inner and outer surfaces of the gloves and the hands of the scrub team members. The detailed listing of bacteria on the hands of the scrub-team members, shown in Table 3.4, indicates that all bacteria were part of the normal skin flora. Overall, normal skin flora was cultured in virtually all hands. There were only two individuals in the whole series in which hands were clean (on both plating and broth culture) at the end of the surgery (operation numbers 4 and 15). In both these cases, the outside of the gloves was also clean. There are two main implications of this finding. Firstly, the standard scrub procedure does not

eliminate normal skin flora from the hands of the scrub team. These bacteria, under the conditions of warmth and moisture within the gloves, must rapidly proliferate to cover the hand skin. Secondly, the normal skin flora on the scrub team members' hands, for the operations in this study, do not appear to be a contributor to morbidity, since no wound infections were found for any of the patients in this study. This is despite the observation that bacteria on the scrub team's hands were detected on the outside of the surgical gloves at the end of a high percentage of cases (246/318 [77.4%] Ansell; 240/278 [86.3%] Profeel). The detection of these bacteria largely in the absense of detectable macroperforations indicates that latex surgical gloves develop microperforations permeable to bacteria during the duration of common surgical procedurtes. The discrepancy in these rates between the two glove brands is analyzed for statistical significance by $\chi^2_{(1)}$ analysis below in Tables 4.14, 4.15 and 4.16. A less likely interpretation of these findings is that the source of detected bacteria was the patient and that gloves commonly allowed penetration to contaminate the wearer's hands. Whilst this may occasionally have been the case (eg. operations 8 and 18 Table 3.4, where additional bacteria occur on glove exteriors compared to interiors), the common finding of bacteria on the glove interiors in the presence of clean glove exteriors suggests the more likely proliferation of wearer's normal skin flora, which not infrequently penetrates to glove exteriors.

Glove Type	Contaminated	Not Contaminated	Total
Ansell	246	72	318
Profeel	240	38	278
Total	486	110	596

Table 4.14: Observed numbers of gloves contaminated on the outside by the wearer's normal skin flora.

Glove Type	Contaminated	Not Contaminated	Total
Ansell	318/596*586 = 259.309	318/596*110 = 58.691	318
Profeel	278/596*486 = 226.691	278/596*110 = 51.309	278
Total	486	110	596

Table 4.15: Calculation of expected numbers of gloves contaminated on the outside by the wearer's normal skin flora, assuming the null hypothesis that there is no significant difference between brands.

Glove Type	Contaminated	Not Contaminated
Ansell	246 - 259.309 = -13.309	72 - 58.691 = 13.309
Profeel	240 - 226.691 = 13.309	38 - 51.309 = -13.309

Table 4.16: Observed - expected calculations for chi-squared statistic with one degree of freedom ($\chi^2_{(1)}$) for comparison of contaminated vs not contaminated gloves

$$\chi^2_{(1)} = \sum (O - E)^2 / E$$

$$= (-13.309)^2/259.309 + (13.309)^2/58.691 + (13.309)^2/226.691 + (-13.309)^2/51.309$$

$$= 7.93$$

$p < 0.01$. Therefore the null hypothesis is rejected, indicating that the 'leak rate' of bacteria from the wearer's skin through to the surface of the gloves was significantly higher for Profeel compared to Ansell gloves. It is likely that this finding relates to differences in the characteristics of the latex used in each type of glove. Despite this finding, there was no apparent

implication of the bacterial leak rate for patients undergoing the types of surgery studied. It is possible that other types of cases may be more liable to morbidity from this effect, eg. neurosurgery or orthopaedic joint surgery. Furthermore, this finding has implications for transmission of bacteria (or viruses) from patient to wearer, where the surgery involves procedures in very contaminated fields. Double-gloving might reduce both macro-perforation rates and this bacterial leak effect. From the point of view of evaluation of gloves however, this study makes clear that evaluation for macroperforations is a narrow criterion which only crudely reflects glove quality or likely performance. It is suggested that the porosity of the latex (or whatever glove material) be subjected to testing which evaluates the development of material saturation and microporosity and leakage resistance to bacteria. Such a test could be devised in a standardized format (eg. immersion of the outer surface of gloves in standardized bacterial suspension for increasing increments of time followed by culture of the inner surface).

4.4 Conclusions

This study has examined two different brands of gloves (Ansell: each glove individually tested for macro-leaks before packaging; Profeel: samples of each batch tested for macro-leaks before packaging) by mechanical testing for macro-leaks, and by microbiologic testing of gloves and wearer's hands, as well as evaluation of wound infections. It has been found that there was one macroperforation in a Profeel glove prior to use, compared to no perforations in unused Ansell gloves. Whilst not statistically significant, clinical significance could be argued.

It has been found that following surgery, the macro-perforation rate for Ansell gloves was higher than for Profeel gloves, that this was statistically significant, and that bias could not be detected in types of wearers or types of operations which could account for this. It could be argued that this might reflect higher mechanical strength of the Profeel material.

A surprising finding was the growth of normal skin flora from virtually every wearer's hands after removing their surgical gloves. This indicates a failure of current hand scrubbing techniques and scrub-solutions to eliminate normal skin flora, which are able presumably to rapidly migrate back to the skin surface from hair follicles and sweat glands and proliferate in the warmth and moisture under the surgical gloves. A further unexpected finding was the very common detection of these bacteria on the outer surface of the wearer's gloves at the end of surgery, whether or not there was a macro-perforation, indicating the development of porosity in latex gloves during common surgical procedures. It is hypothesised that this porosity is a function of saturation of latex with sweat from the wearer's hands and body fluids from the patient, combined with constant movement of the gloves during usage. This combination may intermittently open up micropores which allow bacteria to pass through the barrier. This combination of factors is hypothesised because it would be expected that development of permanent micropores (ie. constantly open rather than intermittently open with movement) would show up as current leakage during electrical testing. The difference in glove micro-porosity (measured by bacterial detection) between the two brands of gloves was statistically significant, indicating a difference in latex properties between the two

brands. It is suggested that a standardized form of this test be developed as a routine quality measure of surgical gloves.

A further unexpected finding was the absence of translation of the macroperforation rates or the inner-to-outer bacterial leakage rates into morbidity (as measured by wound infection) for these types of surgical procedures. It could be concluded from these results that for this type of surgery, the detected differences are irrelevant, leading to cost-per-unit as the deciding factor in choosing glove supplies. However it could alternatively be argued that the detected differences could become significant in selected circumstances, eg. operations in areas highly sensitive to any contamination, or in operations on highly contaminated fields. In these cases, gloves of the lowest macroperforation rating and the lowest rating for development of microporosity would be the deciding factors, and double-gloving could be considered.

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